BALLOON CATHETER FOR EXPANDING CELOM AND ITS PRODUCTION

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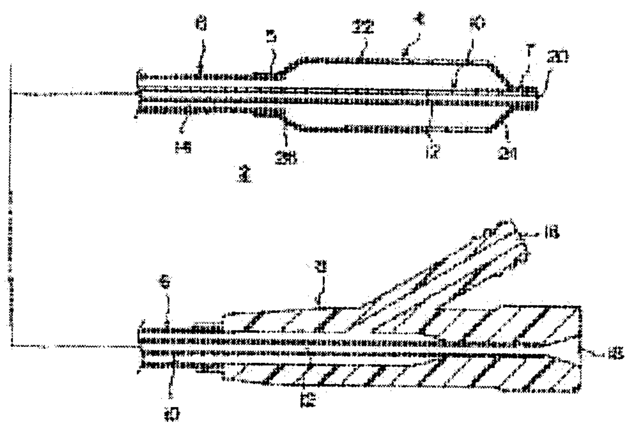
Abstract of **JP 8038618 (A)**

PURPOSE:To provide a balloon catheter for expanding the celom capable of easily and exactly progressing the balloon membrane of the balloon catheter down into the constricted part position of the celom and effectively exhibiting the celom expanding function of the balloon catheter even if the constricted part formed in the celom, such as blood vessel, is narrow, is hard, is eccentric or meanders. CONSTITUTION:The outside diameter at the front end 7 of the cylindrical balloon membrane 4 and the outside diameter in the central part 22 thereof, which are respectively defined as RS and R1, and the film thicknesses at the front end 7 and central part 22 of the cylindrical balloon membrane 4, which are respectively defined as tS and t1, are so set that the relation therebetween satisfies an equation R1Xt1-t1<2>>=0.9X(RSXtS-tS<2>).; Production of the balloon membrane 4 satisfying such relation is executed by first preparing a tubular parison which is larger in the film thickness in the central part than the film thickness at both ends. This parison is then subjected to blow molding.



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CLAIMS

[Claim(s)]
[Claim 1]It is a balloon catheter for abdominal cavity extension which has the tubed balloon membrane which widens a channel in the abdominal cavity by being inserted into the abdominal cavities, such as a blood vessel, and expanding, An outer diameter of a tip part of said tubed balloon membrane and an outer diameter of a center section are made into R_s and R_l, respectively, A balloon catheter for abdominal cavity extension with which relation between these R_s, R_l, t_s, and t_l is satisfied of following the (1) type when thickness of a tip part of said tubed balloon membrane and a center section is made into t_s and t_l, respectively.
[Equation 1]
$R_l x t_l - t_l^2 >= 0.9x (R_s x t_s - t_s^2)$ .... (1)
[Claim 2]A manufacturing method of a balloon catheter for abdominal cavity extension which has the process of forming balloon membrane characterized by comprising the following.
A process which thickness in a center section prepares tube shape thick parison to thickness in both ends.
A tubed balloon membrane center section which carries out blow molding of this parison and where an outer diameter is large.
A tubed tip part and a base end where an outer diameter located in the both ends is small.

[Claim 3]A balloon catheter for abdominal cavity extension characterized by comprising the following with which it is a balloon catheter for abdominal cavity extension, and the diameter of an outer diameter of a tip part of an inner tube to which a tip part of said balloon membrane is connected is reduced smaller than an outer diameter of an inner tube located in a center section of balloon membrane.
Balloon membrane which widens a channel in the abdominal cavity by being inserted into the abdominal cavities, such as a blood vessel, and expanding.
A catheter tube with which the 1st lumen that a tip is connected to a end face of this balloon membrane, introduces a fluid into an inside of the balloon membrane concerned, and swells a balloon part is formed.
An inner tube with which an open end is formed in a tip part, a tip part of said balloon membrane is connected to a periphery of the tip part, said balloon membrane and an inside of a catheter tube are extended in shaft orientations, and the 2nd lumen is formed.

[Translation done.]

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Industrial Application]In this invention, it is inserted into the abdominal cavities, such as a blood vessel, and expands.
Therefore, the balloon catheter which widens the channel in the abdominal cavity is started, and in more detail, in order to treat an intravascular narrow segment, for example, this narrow segment is extended and it is related with the balloon catheter for abdominal cavity extension used for the use which aims at an improvement of the blood flow by the side of narrow segment ****.

[0002]
[Description of the Prior Art]As a balloon catheter for inserting into a blood vessel, extending a narrow segment by swelling balloon membrane, and aiming at an improvement of the blood flow by the side of narrow segment ****, in order to treat an intravascular narrow segment, Many balloon catheters of the excess the wire type in which a guide wire is inserted from the base end of a catheter, and the monorail type which has come out of from outside as a guide wire is a catheter are used. In these types of balloon catheter, a guidewire is previously passed to an intravascular narrow segment, then, a balloon catheter is sent in to a narrow segment along with this guidewire, and a narrow segment is extended by swelling balloon membrane.
[0003]The inner tube with which the lumen to which these types of balloon catheter can insert a guidewire in an inside is formed, It has the catheter tube with which this inner tube was equipped in same axle, and a tip part and a base end, and a base end is attached to the tip part of a catheter tube, and a tip part has the foldable balloon membrane attached to the tip part periphery of an inner tube.
[0004]These types of balloon catheter has the outstanding effect in respect of operativity. In order to extend an intravascular narrow segment and to aim at the blood-flow improvement by the side of a narrow segment end with these types of balloon catheter, it is important to advance a catheter along with the guidewire beforehand inserted into the narrow blood vessel, and to locate balloon membrane in the narrow segment of a blood vessel correctly. As for the tip part of this balloon catheter, since the tip part of the balloon catheter is pressed fit in the very narrow narrow segment, it is preferred that an outer diameter is small so that it may be easy to enter into a narrow segment as possible.
[0005]
[Problem(s) to be Solved by the Invention]However, since balloon membrane is fabricated in the conventional balloon catheter by blow molding (for example, JP,5-192408,A, JP,2-28341,B), it has the following problems. That is, heating the tube shape parison which has uniform thickness in shaft orientations, by introducing a pressure fluid into the inside, parison is swollen and the tubed

balloon membrane 100 as shown in drawing 9 is fabricated in blow molding. The balloon membrane 100 has large outer diameter R_l in the balloon membrane center section 102, and outer diameter R_s becomes small in the tip part 104 and base end 106. The taper part 108,110 is formed between the tip part 104 and the base end 106, and the balloon membrane center section 102.

[0006]If such balloon membrane 100 is fabricated by blow molding from the tube shape parison of uniform thickness to shaft orientations, thickness t_s in the tip part 104 will become thick especially to thickness t_l in the balloon membrane center section 102. In the balloon membrane center section 102 and the tip part 104, it is because the pace of expansion by blow molding is different.

[0007]If the thickness of the tip part 104 is thick, the outer diameter of the tip part of a balloon catheter will become large, and the rigidity in a tip part increases. As a result, it can be hard to push a balloon catheter good to a narrow narrow segment, a hard narrow segment, the narrow segment that carried out eccentricity, or the winding narrow segment.

[0008]If balloon membrane of a balloon catheter cannot be correctly pushed in a narrow segment, the original function of a balloon catheter referred to as extending a narrow segment and improving a blood flow cannot be exhibited. In order to make thin thickness in the tip part of balloon membrane, it is possible to make thin thickness of the tube shape parison before blow molding. However, there is a possibility that the thickness in a balloon membrane center section may change too much thinly after blow molding, and pressure-proofing may become insufficient in that case. Since balloon membrane is designed expand within the abdominal cavities, such as a patient's blood vessel, its pressure-proofing must not be insufficient. Since balloon membrane is folded up and inserted into the abdominal cavities, such as a patient's blood vessel, its thing thin as much as possible is preferred so that easily [insertion into a blood vessel].

[0009]Then, pressure-proofing needs to come out enough and needs to design the thickness of a balloon membrane center section to the thinness of a certain limit. Therefore, the thickness of tube shape parison was determined according to the design thickness of a balloon membrane center section, and it was not avoided that the thickness of the tip part 104 of the balloon membrane 100 becomes thick superfluously.

[0010]To JP,4-176473,A, the stretching process of the balloon membrane is carried out to shaft orientations after blow molding, and the art which makes thickness of the taper part 108,110 thin is indicated in order to make thin thickness of the taper part 108,110 of the balloon membrane 100. However, after blow molding, it is dramatically difficult so to carry out a stretching process that the thickness change of the taper part 108,110 is produced. Though the thickness of the taper part 108,110 is able to be changed temporarily, unless the thickness of the tip part 104 becomes thin, the rigidity of a tip part cannot fully be lowered at the time of insertion in a blood vessel.

[0011]When the narrow segment which this invention was made in view of such the actual condition, and was formed in the abdominal cavities, such as a blood vessel, is narrow, Even when [which is carrying out eccentricity], and it case or moves in a zigzag direction, the catheter tip is flexibly thin enough, It aims at providing a balloon catheter for abdominal cavity extension which it is [balloon catheter] possible to advance balloon membrane of a balloon catheter easily and correctly to the narrow segment position of the abdominal cavity, and can demonstrate the abdominal cavity expanded function of a balloon catheter effectively, and a manufacturing method for the same.

[0012]

[Means for Solving the Problem]To achieve the above objects, the 1st balloon catheter for abdominal cavity extension concerning this invention, It is a balloon catheter for abdominal cavity extension which has the tubed balloon membrane which widens a channel in the abdominal cavity

by being inserted into the abdominal cavities, such as a blood vessel, and expanding, An outer diameter of a tip part of said tubed balloon membrane and an outer diameter of a center section are made into R_s and R_l, respectively, When thickness of a tip part of said tubed balloon membrane and a center section is made into t_s and t_l, respectively, relation between these R_s, R_l, t_s, and t_l satisfies following the (1) type.
[0013]
[Equation 2]
$R_l x t_l - t_l^2 >= 0.9x (R_s x t_s - t_s^2)$ .... (1)
The manufacturing method of the 1st balloon catheter for abdominal cavity extension concerning this invention, To the thickness in both ends, blow molding of the process which the thickness in a center section prepares tube shape thick parison, and this parison is carried out, and it has the process of forming the balloon membrane which has a tubed balloon membrane center section where an outer diameter is large, and the tubed tip part and base end where the outer diameter located in those both ends is small.
[0014]As a method for thickness in a center section to prepare tube shape thick parison to thickness in both ends, a method of carrying out light-gage processing of the both ends of parison of uniform thickness is in shaft orientations before blow molding of parison. A means which heats both ends of parison and it lets pass to a forming die as a means of light-gage processing, and a means to cut both ends of parison by machining can be illustrated. Cutting is easy to work and it is preferred from the ability to carry out light-gage processing of the both ends of parison certainly.
[0015]As the method of others for thickness in a center section to prepare tube shape thick parison to thickness in both ends, a method of equipping a center-section periphery of the 1st parison of uniform thickness with the 2nd parison with a large outer diameter whose shaft-orientations length is shorter than the 1st parison is in shaft orientations.
[0016]After carrying out blow molding of the parison of shaft-orientations uniform thickness and fabricating balloon membrane as an option for manufacturing the 1st balloon catheter for abdominal cavity extension concerning this invention, a method of making thickness of a tip part of balloon membrane thin is by cutting the tip part at least.
[0017]The 2nd balloon catheter for abdominal cavity extension of this invention, Balloon membrane which widens a channel in the abdominal cavity by being inserted into the abdominal cavities, such as a blood vessel, and expanding, A catheter tube with which the 1st lumen that a tip is connected to a end face of this balloon membrane, introduces a fluid into an inside of the balloon membrane concerned, and swells balloon membrane is formed, Have formed an open end in a tip part and a tip part of said balloon membrane is connected to a periphery of the tip part, It is a balloon catheter for abdominal cavity extension which has the inner tube with which said balloon part and an inside of a catheter tube are extended in shaft orientations, and the 2nd lumen is formed, The diameter of an outer diameter of a tip part of an inner tube to which a tip part of said balloon membrane is connected is reduced smaller than an outer diameter of an inner tube located in a center section of balloon membrane.
[0018]As a means for reducing small only the diameter of an outer diameter of a tip part of an inner tube, a means which it lets pass to a forming die, and a means to cut by machining are employable, heating a tip part of an inner tube. A tip part of balloon membrane is connected to a tip part of an inner tube whose diameter was reduced by adhesion, thermal melting arrival, or other means.
[0019]A balloon catheter for abdominal cavity extension is preferably used for percutaneous transluminal coronary angioplasty (PTCA).
[0020]

[Function]The thickness of the tip part of balloon membrane is designed thinly it be satisfied with the 1st balloon catheter for abdominal cavity extension concerning this invention of the above-mentioned (1) formula. The tip part thickness of balloon membrane was fabricated in the conventional example thickly more than needed, in order to secure the thickness of the center section of the balloon membrane after blow molding. In this invention, it becomes possible to fabricate the tip part thickness of balloon membrane thinly, without reducing pressure-proofing of the balloon membrane in a balloon membrane center section by adopting the manufacturing method of above-mentioned this invention.
[0021]If the thickness of the tip part of balloon membrane becomes thin, the outer diameter of the tip part of a balloon catheter will also become small, A narrow narrow segment, a strong narrow segment, or a hard narrow segment can also push a balloon catheter along with a guidewire easily, and can locate balloon membrane correctly in a narrow segment.
[0022]In the 2nd balloon catheter for abdominal cavity extension concerning this invention, since only the diameter of the outer diameter of the tip part of an inner tube is reduced small and adhesion or thermal melting arrival of the tip part of balloon membrane has been carried out to the portion, the outer diameter of the tip part of a balloon catheter becomes still smaller. The tip end part of an inner tube becomes thin meat, and the pliability of the portion improves. As a result, in the balloon catheter of this invention, even if it is the narrow segment which carried out eccentricity to the blood vessel, or the winding narrow segment, when the tip of a balloon catheter bends flexibly, along with a guidewire, it can push good.
[0023]
[Example]Hereafter, the balloon catheter for abdominal cavity extension concerning this invention is explained in detail based on the example shown in a drawing.
The balloon catheter 2 concerning this example shown in 1st example drawing 1 is used for methods, such as an extended way of blood vessels, such as percutaneous transluminal coronary angioplasty (PTCA) and the limbs, an extended way of a top ureter, and a renal vasodilatation way, for example, and it is used in order to extend the narrow segment formed in a blood vessel or the other abdominal cavities. The following explanation explains as an example the case where the balloon catheter 2 of this example is used for PTCA.
[0024]The balloon catheter 2 for extension of this example has the balloon membrane 4, the catheter tube 6, the tee 8, and the inner tube 10. The base end 5 of the balloon membrane 4 is connected to the tip part of the catheter tube 6, and the tee 8 is connected to the base end of the catheter tube 6.
[0025]The tip part 7 of this balloon membrane 4 is connected to the tip part periphery of the inner tube 10. Connection between the balloon membrane 4 and the inner tube 10 and connection between the balloon membrane 4 and the catheter tube 6 are made by join means, such as thermal melting arrival or adhesion. In order to insert a guidewire etc. in the inside of the inner tube 10, 12 [lumen / 2nd] is formed. The inner tube 10 is prolonged in shaft orientations in the state of the abbreviated same axle in the inside of the balloon membrane 4, the catheter tube 6, and the tee 8. Inside the catheter tube 6, 14 [lumen / 1st] is formed between the catheter tube 6 and the inner tube 10. The expansional port 16 currently formed in the tee 8 is open for free passage, and from there, a pressure fluid is introduced into 14 and swells the 1st lumen of the folded-up balloon membrane 4 to it.
[0026]Especially as a pressure fluid introduced in 1st lumen 14 through the expansional port 16, although not limited, 50/50 mixed water solution of radiopaque dye and salts, etc. are used, for example. It is for using radiation and imaging the position of the balloon membrane 4 and the catheter tube 6 at the time of use of the balloon catheter 2, to include radiopaque dye. Although the pressure in particular of the pressure fluid for swelling the balloon membrane 4 is not limited, it is about 4-8 atmospheres preferably 3-12 atmospheres in absolute pressure.
[0027]Along with the axial center of the inner tube 10, the guide port 18 is formed in the tee 8

separately [the expansional port 16]. The base end side open end of the inner tube 10 is connected to the tee 8 so that this guide port 18 may be open for free passage in the 2nd lumen 12 currently formed in the inner tube 10. Connection between the catheter tube 6 and the tee 8 and connection between the inner tube 10 and the tee 8 are made by thermal melting arrival, adhesion, or other means.

[0028]As for the catheter tube 6, it is preferred to comprise construction material which has a certain amount of flexibility, For example, polyethylene, polyethylene terephthalate, polypropylene, Ethylene propylene rubber, an ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), A constructed type ethylene-vinylacetate copolymer of a bridge, polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and it comprises polyethylene, polyamide, and polyimide preferably. Although homogeneity may be sufficient as the outer diameter of the catheter tube 6, it is small to shaft orientations at a balloon membrane 4 close-attendants side, and it may form a step or a taper part in them on the way so that it may become large in other portions. By enlarging the 1st lumen of the passage cross section of 14, it is for shortening the time which shrinks the balloon membrane 4. After the balloon membrane 4 expands about 1 minute, it is because it is required to make it contract immediately, and is for securing the blood flow by the side of a tip.

[0029]As for the outer diameter of the catheter tube 6, near the terminal area with the balloon membrane 4, about 0.6-1.0 mm is preferred, and its about 0.8-1.2 mm is preferred in the tee 8 side. As for the thickness of the catheter tube 6, about 0.05-0.15 mm is preferred. The inner tube 10 may comprise the same construction material as the catheter tube 6, for example, and comprises polyethylene, polyamide, and polyimide preferably. As a reinforcing member, stainless lines, a nickel titanium alloy line, etc. may be used. Especially if the inside diameter of this inner tube 10 is a path which can insert in a guidewire, it will not be limited, for example, it is 0.25-0.60 mm preferably 0.15-1.00 mm. As for the thickness of this inner tube 10, 0.05-0.15 mm is preferred. Although the overall length of the inner tube 10 is determined according to the shaft-orientations length etc. of the balloon catheter 2 inserted into a blood vessel and is not limited in particular, it is about 130-140 mm preferably 120-150 mm, for example. The open end 20 is formed in the tip part of the inner tube 10. It is possible to draw the guidewire which inserted in the inside of 2nd lumen 12 of the inner tube 10 from this open end 20.

[0030]The circumference of the inner tube 10 located in the balloon membrane 4 can also be equipped with a radiopacity marker at one place or two or more places. As this marker, it can be with a metal tube, a metal spring, etc. which comprise gold, platinum, tungsten, iridium, or these alloys, for example. By attaching this marker to the circumference of the inner tube 10 in balloon membrane, the length of the position of the balloon membrane 4 or the extension of a balloon is detectable under the radioscopy at the time of use of the balloon catheter 2.

[0031]The tee 8 is suitably fabricated, for example with thermoplastics, such as polycarbonate, polyamide, poly SARUHON, polyacrylate, and a methacrylate butylene-styrene copolymer. The tubed balloon membrane center section 22 where the balloon membrane 4 has uniform outer diameter R_l (at the time of balloon membrane expansion) in shaft orientations in this example as shown in drawing 1 and 2, It is provided in the both ends and has the tubed tip part 7 and the base end 5 which have outer diameter R_s smaller than the balloon membrane center section 22 and R_s', respectively. The tip part 7 and the base end 5, and the balloon membrane center section 22 are continuously fabricated by the taper parts 24 and 26 which have reduced the diameter of an outer diameter to shaft orientations at ****.

[0032]Although thickness t_l in particular in the balloon membrane center section 22 of the balloon membrane 4 is not limited, about tens of micrometers are preferably preferred 15-200 micrometers. As long as the balloon membrane 4 is cylindrical, it may not be limited in particular

but a cylinder or the shape of a multiple cartridge may have as it. Outer diameter R_l in the balloon membrane center section 22 of the balloon membrane 4 at the time of expansion is determined by factors, such as an inside diameter of a blood vessel, and its about 1.5-4.0 mm is preferred. Although shaft-orientations length L of the balloon membrane center section 22 of this balloon membrane 4 is determined by factors, such as a size of an intravascular narrow segment, and is not limited in particular, it is 20-40 mm preferably 15-50 mm. The balloon membrane 4 before expanding is folded up around the inner tube 10 shown in drawing 1, is twisted, and has become an outer diameter of the catheter tube 6, and below equivalent.
[0033]As for the construction material which constitutes the balloon membrane 4, it is preferred that it is the construction material which has a certain amount of flexibility, For example, polyethylene, polyethylene terephthalate, polypropylene, Ethylene propylene rubber, an ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), A constructed type ethylene-vinylacetate copolymer of a bridge, polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and they are polyethylene, polyethylene terephthalate, and polyamide preferably.
[0034]As shown in drawing 2, in this example the outer diameter of the tip part 7 of the balloon membrane 4, and the outer diameter of the center section 22, Consider it as R_s and R_l, respectively, and the thickness of the tip part 7 of the balloon membrane 4, and the center section 22, When it is considered as t_s and t_l, respectively, the relation between these R_s, R_l, t_s, and t_l is set up satisfy following the (1) type. The method for manufacturing balloon membrane so that following the (1) type may be satisfied is mentioned later.
[0035]
[Equation 3]
$R_l x t_l - t_l >= 0.9x\ (R_s x t_s - t_s^2)$ .... (1)
In the balloon membrane of the conventional balloon catheter, from balloon membrane being manufactured by the usual blow molding, as shown in below-mentioned drawing 3, the relation of following the (2) type was suited.
[0036]
[Equation 4]
$R_l x t_l - t_l^2 = R_s x t_s - t_s^2$ .... (2)
The meaning of the above-mentioned (2) formula is that the area (left side of the formula 2) of the film cross section in the center section 22 of the balloon membrane 4 is equal to the area (right-hand side of the formula 2) of the film cross section in the tip part 7 of the balloon membrane 4, for example in drawing 2. Since the conventional balloon membrane is fabricated by carrying out blow molding of the parison of shaft-orientations uniform thickness, the above-mentioned (2) formula is realized.
[0037]In this example, since the above-mentioned balloon membrane 4 was manufactured by adopting a process which is mentioned later, thickness t_s of the tip part 7 of the balloon membrane 4 was able to be made thin so that the above-mentioned (1) formula might be satisfied. Also about thickness t_s' of the base end 5 of the balloon membrane 4, it can fabricate in this example thinly so that following the (3) type may be satisfied.
[0038]
[Equation 5]
$R_l x t_l - t_l^2 >= 0.9x\ (R_s' x t_s' - t_s'^2)$ -- (3)
Next, the manufacturing method of the balloon membrane 4 shown in drawing 2 is explained. First, as shown in drawing 3 (A), thickness and outer diameter R_0 prepares the tube shape

uniform parison 4a in shaft orientations. Although outer diameter R_0 in particular of the parison 4a is not limited, it is 0.5-1.5 mm preferably 0.2-2.0 mm. Although the thickness in particular of the parison 4a is not limited, it is 0.3-0.7 mm preferably 0.2-0.9 mm. Although length L_0 in particular of the parison 4a is not limited, it is 20-300 mm preferably 10-500 mm.
[0039]Next, as shown in drawing 3 (B), light-gage processing of the both ends 5a and 7a of the parison 4a is carried out. The method of heating the both ends 5a and 7a of the parison 4a, and letting it pass to a forming die as the method of light-gage processing, and the method of cutting the both ends 5a and 7a of the parison 4a by machining can be illustrated. In the method of letting it pass to a forming die, the inside diameter of the parison 4a does not change by using a mandrel. Cutting is easy to work and it is preferred from the ability to carry out light-gage processing of the both ends of parison certainly.
[0040]The outer diameter of the both ends 5a and 7a after light-gage processing is 0.4-1.2 mm preferably 0.2-1.6 mm. The thickness is 100 to 300% preferably 50 to 400% to the thickness in a parison center section.
Specifically, it is 0.1-0.3 mm preferably 0.05-0.40 mm.
Length range L_1 of the both ends 5a and 7a by which light-gage processing is carried out is 2-50 mm preferably 1-100 mm.
[0041]Then, while these both ends equip with the parison by which light-gage processing was carried out in a blow molding public-funds type and heat it, pressure gas or a pressure liquid is poured inside the parison 4a, blow molding is performed, and the balloon membrane 4 of shape as shown in drawing 2 is formed. Next, how to perform a PTCA therapy is explained using the balloon catheter 2 of the example shown in drawing 1.
[0042]First, the air in the balloon catheter 2 is removed as much as possible. then, the guide port 18 of the tee 8 to the inside of the inner tube 10 -- the 2nd lumen of fluids, such as a physiological saline, are put into 12, and the air in 2nd lumen 12 is replaced. To the expansional port of the tee 8, suction and injection means, such as a syringe, are attached, fluids, such as a blood contrast medium (for example, iodine content), are put in in a syringe, suction and pouring are repeated, and the air in 1st lumen 14 and the balloon membrane 4 is replaced by a fluid at it.
[0043]In order to insert the balloon catheter 2 into an arterial blood pipe, the guidewire for guide catheters (not shown) is first inserted into a blood vessel by Seldinger method etc. so that the tip may arrive to near the heart. Then, along with the guidewire for guide catheters, the guide catheter 32 shown in drawing 4 is inserted into the arterial blood pipe 34, and the tip is located in the coronary artery entrance 40 of the heart 38 which has the narrow segment 36. The narrow segment 36 is formed, for example of a thrombus or arteriosclerosis.
[0044]Next, only the guidewire for guide catheters is sampled, the guidewire 42 for balloon catheters thinner than it is inserted along with the guide catheter 32, and the tip is inserted to the position which passes the narrow segment 36. Then, the end face of the guidewire 42 shown in drawing 4 is inserted in the open end 20 of the balloon catheter 2 shown in drawing 1, and where through and the balloon membrane 4 are folded up in 2nd lumen 12 of the inner tube 10, it lets the balloon catheter 2 pass in the guide catheter 32 shown in drawing 4. And the balloon membrane 4 of the balloon catheter 2 is inserted to this side of the narrow segment 36, as shown in drawing 4. Or after extracting the guidewire for guide catheters from the guide catheter 32, The balloon catheter which inserted in the guidewire in 2nd lumen 12 of an inner tube from the guide port 18 of the tee may be inserted from the base of the guide catheter shown in drawing 4, the balloon membrane 4 may be drawn in a coronary artery, and the tip of the guidewire 42 may also be inserted to the position which passes the narrow segment 36.
[0045]Then, as shown in drawing 5 (A), the tip part 7 of the balloon membrane formed in the tip of the balloon catheter 2 is inserted between the narrow segments 36 along with the guidewire 42. In that case, the thickness of the tip part 7 of the balloon membrane 4 from a thin thing by

this example. When the outer diameter is small and the gap of the guidewire 42 and the narrow segment 36 is small, as shown in drawing 5 (B) and (C), the balloon catheter 2 can be easily pushed also by the strong narrow segment or a hard narrow segment. Since the reaction force generated when pushing the balloon catheter 2 in the narrow segment 36 is received when the tip side bending part 44 of the guide catheter 32 shown in drawing 4 contacts the wall of the blood vessel 34, it is preferred that this reaction force is small. In this example, this reaction force becomes small.

[0046]Next, the balloon membrane 4 is correctly located in the center section of the narrow segment 36, observing the position of the balloon membrane 4 with an X-ray fluoroscope etc., as shown in drawing 5 (C). By swelling the balloon membrane 4 in the position, the narrow segment 36 of the blood vessel 34 can be extended, and a good therapy can be performed. In order to swell the balloon membrane 4, it lets 14 [lumen / 1st] pass from the expansional port 16 shown in drawing 1, and carries out by pouring in fluids, such as a contrast medium, into the balloon membrane 4.

[0047]Although this expansion time in particular is not limited, it is a for [about 1 minute] grade, for example. Then, a fluid is promptly drained from the balloon membrane 4, balloon membrane is shrunk, and the blood flow by the side of the tip of the extended narrow segment 36 is secured. To the same narrow segment 36, although expansion of the balloon membrane 4 is 1 time, depending on the conditions of the narrow segment 36, multiple times may usually be sufficient as it.

[0048]Next, other examples of this invention are described.

2nd example this example is related with the manufacturing method of others of the balloon membrane 4 shown in drawing 2. Since it is the same as that of the 1st example of the above except the manufacturing method of the balloon membrane 4, the explanation is omitted.

[0049]In this example, as shown in drawing 6, the parison 4b by which the diameter of both ends was reduced is prepared by equipping the center-section periphery of the 1st parison 28 with the 2nd parison 30, and carrying out adhesion or thermal melting arrival of these to it. The parison 4b has as a result the parison 4a and the identical size which are shown in drawing 3 (B).

[0050]After that, the balloon membrane 4 shown in drawing 2 can be formed like the 1st example.

In 3rd example this example, after manufacturing balloon membrane by the same method as usual, those light-gage processings are performed by the method of letting it pass to a forming die, heating the tubed tip part and tubed base end of the method of carrying out machinery cutting of the periphery of the tubed tip part of balloon membrane, and a tubed base end, or balloon membrane. The balloon membrane 4 shown in drawing 2 concerning the 1st example of the above also by such a method can be manufactured.

[0051]Other processes and structures are the same as that of the 1st example of the above. As compared with the balloon catheter 2 of the example shown in drawing 1, it is that the joining structure of the balloon membrane 4A, the inner tubes 10A, and these tip parts is only different, and the other composition of the balloon catheter 2A concerning the example shown in 4th example drawing 7 is the same. So, identical codes are given to the member which is common in the balloon catheter 2 of the example shown in drawing 1, and a part of the explanation is omitted to it. It is the same as that of the 1st example of the above except describing to below specially about construction material, a size, etc. of the balloon membrane 4A and the inner tube 10A.

[0052]As for the balloon membrane 4A, in the balloon catheter 2A of this example, it is preferred that the tip part 7b and base end 5b fabricate thinly like the balloon membrane shown in drawing 2 compared with the former so that the above-mentioned (1) formula and (2) types may be satisfied. However, in this example, since the portion is not the point, the same thickness as usual may be sufficient as the tip part 7b and the base end 5b of the balloon membrane 4A.

[0053]In this example, as shown in drawing 8 (A) and (B), as compared with the outer diameter of other portions (inner tube 10A located in the center section of the balloon membrane 4A shown in drawing 7), the diameter of the outer diameter of the tip part 70 of the inner tube 10A is reduced small. As for the inside diameter of the inner tube 10A, since a guidewire is inserted in, it is preferred to shaft orientations that it is approximately regulated. Therefore, in the tip part 70 of the inner tube 10A, the thickness becomes thinner than other portions.
[0054]The inside diameter of the inner tube 10A is 0.25-0.60 mm preferably 0.15-1.00 mm like the case of said 1st example, for example. The thickness of inner tubes 10A other than tip part 70 is 0.05-0.15 mm.
30 to 70% of the thickness in the tip part 70 is desirable to thickness other than this tip part 70, and, specifically, its 0.05-0.10 mm is preferred.

[0055]As for length L_2 of the tip part 70 in the inner tube 10A whose diameter was reduced, it is preferred that they are the length equivalent to a terminal area with the tip part 7b of the balloon membrane 4A shown in drawing 1 or length longer than it, and, specifically, its 2-20 mm is preferred. A drawing stretching process or an extrusion stretching process using mechanical cutting or the forming die, and the mandrel as a means for reducing the diameter of the tip part 70 of the inner tube 10A etc. can be used.
[0056]In the balloon catheter 2A concerning this example, since only the diameter of the outer diameter of the tip part 70 of the inner tube 10A is reduced small and adhesion or thermal melting arrival of the tip part 7b of the balloon membrane 4A has been carried out to the portion, the outer diameter of the tip part of the balloon catheter 2A becomes small. The tip part 70 of the inner tube 10A becomes thin meat, and the pliability of the portion improves. As a result, in the balloon catheter 2A of this example, even if it is the narrow segment which carried out eccentricity to the blood vessel, or the winding narrow segment, when the tip of the balloon catheter 2A bends flexibly, along with a guidewire, it can push good.
[0057]this invention is not limited to the example mentioned above, within the limits of this invention, can be boiled variously and can be changed. For example, although each above-mentioned example explained as an example the case where the balloon catheter concerning this invention was used for a PTCA cure, the balloon catheter concerning this invention can be widely used, in order to extend the abdominal cavity of the blood vessel or others in which the narrow segment etc. were formed.
[0058]Next, although this invention is explained still more concretely, this invention is not limited to these examples.
The balloon was fabricated using the tube of Example 1 and comparative example 1 Nylon 11.
[0059]The line elastic moduli of used Nylon 11 were about 4500 kg/cm. As shown in drawing 10, perform machinery cutting of both ends, and R_l 1.125 mm, R_s=R_s' prepared the tube before balloon shaping of the size whose Lc of 0.374 mm and t_l 40 mm and Lb are 30 mm and 0.4 mm and La is [1.072 mm and R_d / 0.325 mm and t_s'=t_s] 20 mm.
[0060]This tube was put into the mold, heat pressing was performed for about 10 seconds by 184 ** and 7 kg/cm^2, and balloon membrane was fabricated. The tip part and the hand part were cut after shaping using the cutting machine. The balloon membrane (example 1) after cutting is 3 mm in outer diameter of a center section, and is 0.1 mm in thickness.
The outer diameter of the tip part was set to 1.2 mm, and thickness was set to 0.30 mm.
The size of the hand part was 0.23 mm in 1.36 mm and thickness in the outer diameter. Except not cutting both ends after the heat pressing within a mold, like the above-mentioned, the size of the balloon membrane (comparative example 1) after shaping was 1.42 mm in the outer diameter of 0.42 mm and a hand part, was 1.60 mm in thickness, and was [the outer diameter of the tip

part] 0.35 mm in thickness.
[0061]Two kinds of this balloon membrane (Example 1 and the comparative example 1) was connected to the catheter tube which consists of the outer tube and inner tube made from polyethylene, respectively. The line elastic coefficients of the used polyethylene were about 1000 kg/cm. The inner-tube tube which connected the tip part of balloon membrane is a with the outer diameter of 0.6 mm, and a thickness of 0.08 mm thing.
The outer-tube tube which connected the hand end part was a with the outer diameter of 0.9 mm, and a thickness of 0.08 mm thing.
Elastic polyurethane rubbers were used as adhesives. In this example, it is $R_l x t_l - t_l^2$=0.29, It is 0.9 $(R_s x t_s - t_s^2)$= 0.243, and is a formula. $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied.
[0062]On the other hand, it is $R_l x t_l - t_l^2$=0.29, and is $0.9(R_s x t_s - t_s^2)$= 0.378, and the above-mentioned (1) formula is not filled with the comparative example 1. Next, it bent to 2.5 mm in inside diameter and the curvature radius of 10 mm which were immersed into warm water, and the experiment which inserts in the balloon catheter of Example 1 and the comparative example 1 in the hard tube made from polyvinyl chloride which imitated and created the blood vessel was conducted.
[0063]The result tried 10 times respectively is shown.
[0064]
[Table 1]

	挿通した	挿通せず
(両端加工例) 実施例 1	8	2
(両端未加工例) 比較例 1	3	7

[0065]As shown in the above-mentioned table, this difference originates in the size, especially tip thickness at the tip of a balloon. Although the thickness difference near a tip is slight, when it is made to insert in by Example 1 and the comparative example 1 in the hard tube which imitated the curvature radius of 10 mm, and the blood vessel distorted strongly, in this example, the rigidity at the tip of a catheter becomes low on structural mechanics.
[0066]Under the conditions to which transfer of the power pushed in with a soft catheter tube is restricted, it is thought according to this example 1 and the comparative example 1 that the difference arose in the ease of inserting in. In clinical [actual], since the blood vessel inside diameter is also ****(ed) remarkably, then, it is considered to work in favor of the insertion nature of a catheter that the balloon tip outer diameter by this example is also small.
[0067]R_l in the tube shown in example 2 drawing 10 1.125 mm, R_d created the tube of Nylon 11 of the size which 0.346 mm calls 1.017 mm in 0.325 mm and $t_s = t_s'$, and 0.4 mm and $R_s = R_s'$ say in t_l. Using this tube, balloon membrane was fabricated like Example 1 and post forming both ends were cut. The outer diameter by the side of the tip part of a balloon, a center section, and a hand part and thickness were 1.13 mm (outer diameter)/0.27 mm (thick), 3.00 mm (outer diameter)/0.10 mm (thick), and 1.32 mm (outer diameter)/0.21 mm (thick) respectively. In this example, it is $R_l x t_l - t_l^2$=2.9, it is $0.9(R_s x t_s - t_s^2)$= 0.20897 -- formula $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied. This balloon membrane was connected to the catheter shown in Example 1, and insertion in the imitation blood vessel shown in Example 1 was tried 10 times. A result is shown in Table 2.

[0068]
[Table 2]

	挿通した	挿通せず
実施例 2	1 0	0

[0069]The tube of Nylon 11 as shown in Examples 3 and 4 and two or less comparative example was prepared, and balloon membrane was fabricated. The line elastic coefficients of used Nylon 11 were about 4500 kg/cm. The tube of Examples 3 and 4 cut both ends mechanically, as illustrated to drawing 10, and it made them the predetermined outer diameter.
[0070]After having put these tubes into the mold, carrying out heat pressing like Example 1 and fabricating a balloon, using the cutting machine, the tip part and the hand part were cut and it was considered as a predetermined outer diameter and thickness. Any balloon membrane of the thickness in 3.0 mm and the portion of those of the outer diameter of the balloon center section was 0.16 mm.
[0071]The tube dimensions for fabricating the balloon membrane of Example 3, 0.325 mm and $t_s=t_s'$ are 0.374 mm and 1.073 mm and R_d is [R_l / t_l of 1.37 mm and $R_s=R_s'$] 0.53 mm in drawing 10. The outer diameter of the balloon center section of the balloon membrane after shaping is 3.0 mm, thickness is 0.16 mm, and they are 1.36 mm in outer diameter, and 0.23 mm in thickness in a tip part at the outer diameter of 1.20 mm, the thickness of 0.30 mm, and a hand part. In this example, it is $R_l x t_l - t_l^2=0.4544$, It is $0.9(R_s x t_s - t_s^2)= 0.243$, and is a formula. $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied. The tube dimensions for fabricating the balloon membrane of Example 4, 0.325 mm and $t_s= t_s'$ are 0.495 mm, and 1.31 mm and R_d is [R_l / t_l of 1.39 mm and $R_s=R_s'$] 0.53 mm in drawing 10. The outer diameter of the balloon center section of the balloon membrane after shaping is 3.0 mm, thickness is 0.16 mm, and they are 1.56 mm in outer diameter, and 0.33 mm in thickness in a tip part at the outer diameter of 1.41 mm, the thickness of 0.40 mm, and a hand part. In this example, it is $R_l x t_l - t_l^2=0.4544$, It is $0.9(R_s x t_s - t_s^2)= 0.3636$, and is a formula.
$R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied.
[0072]In the comparative example 2, it is made the same in Example 4 except not cutting both ends after the heat pressing within a mold, The outer diameter of the balloon center section fabricated 3.0 mm, and thickness fabricated with the outer diameter of 1.71 mm, and a thickness of 0.40 mm balloon membrane by the outer diameter of 1.57 mm, the thickness of 0.48 mm, and a hand part by 0.16 mm and a tip part.
[0073]In this comparative example, it is $R_l x t_l - t_l^2=0.4544$, It is $0.9(R_s x t_s - t_s^2)= 0.47088$, and is a formula. $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is not satisfied. These kinds of balloon membrane was connected to the catheter tube made from polyethylene like Example 1.
[0074]The line elastic coefficients of the used polyethylene were about 1000 kg/cm. The outer-tube tube which connected the inner-tube tube linked to a balloon tip part to the outer diameter of 0.6 mm, the thing with a thickness of 0.08 mm, and the balloon hand end part was a with the outer diameter of 0.9 mm, and a thickness of 0.08 mm thing. Elastic polyurethane rubbers were used as adhesives.
[0075]Next, it bent to 2.5 mm in inside diameter and the curvature radius of 10 mm which were immersed into warm water, and the experiment which inserts in the balloon catheter of these

examples and a comparative example in the hard tube made from polyvinyl chloride which imitated and made the blood vessel was conducted. Respectively, the result tried 10 times is shown in Table 3.
[0076]
[Table 3]

	挿通した	挿通せず
実施例 3	10	0
実施例 4	8	2
比較例 2	2	8

[0077]As shown in Table 3, the difference large in the insertion characteristic was seen by the example and the comparative example. This difference originates in the size at the tip of a balloon, especially thickness. Although the thickness difference near a tip is only 0.08 mm, when it is made to insert in in an example and a comparative example in the hard tube which imitated the curvature radius of 10 mm, and the blood vessel distorted strongly, in this example, the rigidity at the tip of a catheter is low.
[0078]Under these conditions to which transfer of the power pushed in with a soft catheter tube is restricted, it is thought that the direction of Example 4 produced the difference in the ease of inserting in compared with the comparative example. It is based on the same reason that especially Example 3 was excellent. In clinical [actual], since the blood vessel inside diameter is also ****(ed) remarkably, it is then considered to work in favor of the insertion nature of a catheter that the balloon tip outer diameter by this example is also small.
[0079]R_l shown in drawing 10 by the method of letting a tube pass to Example 5 and the die heated comparative example 3 1.125 mm, $R_s'=R_s$ created the tube of Nylon 11 whose t_l 0.325 mm and $t_s=t_s'$ are 0.346 mm and 1.017 mm and R_d is 0.4 mm.
[0080]After carrying out heat pressure molding with a metallic mold like Example 1 using this tube, the tip part and the hand part were cut with the cutting machine, and balloon membrane was created. The outer diameter by the side of the tip part of balloon membrane, a center section, and a hand part and thickness were respectively set to 1.13 mm (outer diameter)/0.27 mm (thick), 3.00 mm (outer diameter)/0.10 mm (thick), and 1.32 mm (outer diameter)/0.21 mm (thick). In this example, it is $R_l x t_l - t_l^2=0.29$, it is $0.9(R_s x t_s - t_s^2)= 0.209$ -- formula $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied. The catheter tube made from polyethylene shown in previous Examples 3 and 4 was connected to this.
[0081]The balloon membrane fabricated not reducing thickness of both ends as a comparative example (without it cuts) was similarly connected to said catheter tube made from polyethylene. An outer diameter and the thickness of the size of the tip part, the center section, and the hand part were 1.48 mm (outer diameter)/0.44 mm (thick), 3.00 mm (outer diameter)/0.10 mm (thick), and 1.64 mm (outer diameter)/0.37 mm (thick).
[0082]In a comparative example, it is $R_l x t_l - t_l^2=0.29$, it is $0.9(R_s x t_s - t_s^2)= 0.412$ -- formula $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is not satisfied. Insertion in the imitation blood vessel which used these catheters in the example 3 grade was tried 10 times respectively. A result is shown in Table 4.
[0083]
[Table 4]

	挿通した	挿通せず
実施例 5	1 0	0
比較例 3	3	7

[0084]Only the diameter of the tip part of a with example 6 outer diameter of 0.6 mm and a thickness of 0.08 mm tube was reduced by cutting etc., it was made into the outer diameter of 0.52 mm, and the thickness of 0.04 mm (other portions the outer diameter of 0.6 mm, thickness of 0.08 mm), and the inner tube of the balloon catheter was fabricated.
[0085]Apart from this, R_l shown in drawing 10 like Example 4 1.39 mm, R_s=R_s' formed the tube whose t_l 0.325 mm and t_s=t_s' are 0.495 mm and 1.31 mm and R_d is 0.53 mm by cutting. After carrying out heat pressure molding of this tube within a metallic mold, cut it and The tip part of balloon membrane, The size of the center section and the hand part fabricated 1.37 mm (outer diameter)/0.43 mm (thick), 3.00 mm (outer diameter)/0.16 mm (thick), and 1.56 mm (outer diameter)/0.33 mm (thick) of balloon membrane.
[0086]This balloon membrane was connected to the inner tube (tube with which the tip part of the inner tube became thin) and outer tube (it is the same as Example 1) of said balloon catheter, the catheter was assembled like Example 1, and it examined by the same method as Example 1. A result is shown in Table 5.
[0087]
[Table 5]

	挿通した	挿通せず
実施例 6	9	1

[0088]In this example, the tip outer diameter of the balloon is thin 0.04 mm (about 3%) by having reduced the diameter of an inner-tube tube compared with Example 4. It is expected that this will have good insertion nature at the time of application in the blood vessel which ****(ed) in clinical [actual].
[0089]
[Effect of the Invention]As explained above, when the narrow segment formed in the abdominal cavities, such as a blood vessel, is narrow according to this invention, When a narrow segment is hard, eccentricity or even when it moves in a zigzag direction, a narrow segment can advance balloon membrane of a balloon catheter easily and correctly by a low operating physical force to the narrow segment position of the abdominal cavity, and can demonstrate the abdominal cavity expanded function of a balloon catheter effectively.
[0090]In the manufacturing method of the balloon catheter concerning this invention, it becomes possible to fabricate the tip part thickness of balloon membrane thinly, without reducing pressure-proofing of the balloon membrane in a balloon membrane center section.

[Translation done.]

* NOTICES *

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1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

PRIOR ART

[Description of the Prior Art]As a balloon catheter for inserting into a blood vessel, extending a narrow segment by swelling balloon membrane, and aiming at an improvement of the blood flow by the side of narrow segment ****, in order to treat an intravascular narrow segment, Many balloon catheters of the excess the wire type in which a guide wire is inserted from the base end of a catheter, and the monorail type which has come out of from outside as a guide wire is a catheter are used. In these types of balloon catheter, a guidewire is previously passed to an intravascular narrow segment, then, a balloon catheter is sent in to a narrow segment along with this guidewire, and a narrow segment is extended by swelling balloon membrane.
[0003]The inner tube with which the lumen to which these types of balloon catheter can insert a guidewire in an inside is formed, It has the catheter tube with which this inner tube was equipped in same axle, and a tip part and a base end, and a base end is attached to the tip part of a catheter tube, and a tip part has the foldable balloon membrane attached to the tip part periphery of an inner tube.
[0004]These types of balloon catheter has the outstanding effect in respect of operativity. In order to extend an intravascular narrow segment and to aim at the blood-flow improvement by the side of a narrow segment end with these types of balloon catheter, it is important to advance a catheter along with the guidewire beforehand inserted into the narrow blood vessel, and to locate balloon membrane in the narrow segment of a blood vessel correctly. As for the tip part of this balloon catheter, since the tip part of the balloon catheter is pressed fit in the very narrow narrow segment, it is preferred that an outer diameter is small so that it may be easy to enter into a narrow segment as possible.

[Translation done.]

EFFECT OF THE INVENTION

[Effect of the Invention]As explained above, when the narrow segment formed in the abdominal cavities, such as a blood vessel, is narrow according to this invention, When a narrow segment is hard, eccentricity or even when it moves in a zigzag direction, a narrow segment can advance balloon membrane of a balloon catheter easily and correctly by a low operating physical force to the narrow segment position of the abdominal cavity, and can demonstrate the abdominal cavity expanded function of a balloon catheter effectively.
[0090]In the manufacturing method of the balloon catheter concerning this invention, it becomes possible to fabricate the tip part thickness of balloon membrane thinly, without reducing pressure-proofing of the balloon membrane in a balloon membrane center section.

[Translation done.]

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]However, since balloon membrane is fabricated in the conventional balloon catheter by blow molding (for example, JP,5-192408,A, JP,2-28341,B), it has the following problems. That is, heating the tube shape parison which has uniform thickness in shaft orientations, by introducing a pressure fluid into the inside, parison is swollen and the tubed balloon membrane 100 as shown in drawing 9 is fabricated in blow molding. The balloon membrane 100 has large outer diameter R_l in the balloon membrane center section 102, and outer diameter R_s becomes small in the tip part 104 and base end 106. The taper part 108,110 is formed between the tip part 104 and the base end 106, and the balloon membrane center section 102.
[0006]If such balloon membrane 100 is fabricated by blow molding from the tube shape parison of uniform thickness to shaft orientations, thickness t_s in the tip part 104 will become thick especially to thickness t_l in the balloon membrane center section 102. In the balloon membrane center section 102 and the tip part 104, it is because the pace of expansion by blow molding is different.
[0007]If the thickness of the tip part 104 is thick, the outer diameter of the tip part of a balloon catheter will become large, and the rigidity in a tip part increases. As a result, it can be hard to push a balloon catheter good to a narrow narrow segment, a hard narrow segment, the narrow segment that carried out eccentricity, or the winding narrow segment.
[0008]If balloon membrane of a balloon catheter cannot be correctly pushed in a narrow segment, the original function of a balloon catheter referred to as extending a narrow segment and improving a blood flow cannot be exhibited. In order to make thin thickness in the tip part of balloon membrane, it is possible to make thin thickness of the tube shape parison before blow molding. However, there is a possibility that the thickness in a balloon membrane center section may change too much thinly after blow molding, and pressure-proofing may become insufficient in that case. Since balloon membrane is designed expand within the abdominal cavities, such as a patient's blood vessel, its pressure-proofing must not be insufficient. Since balloon membrane is folded up and inserted into the abdominal cavities, such as a patient's blood vessel, its thing thin as much as possible is preferred so that easily [insertion into a blood vessel].
[0009]Then, pressure-proofing needs to come out enough and needs to design the thickness of a balloon membrane center section to the thinness of a certain limit. Therefore, the thickness of tube shape parison was determined according to the design thickness of a balloon membrane center section, and it was not avoided that the thickness of the tip part 104 of the balloon membrane 100 becomes thick superfluously.
[0010]To JP,4-176473,A, the stretching process of the balloon membrane is carried out to shaft orientations after blow molding, and the art which makes thickness of the taper part 108,110 thin is indicated in order to make thin thickness of the taper part 108,110 of the balloon

membrane 100. However, after blow molding, it is dramatically difficult so to carry out a stretching process that the thickness change of the taper part 108,110 is produced. Though the thickness of the taper part 108,110 is able to be changed temporarily, unless the thickness of the tip part 104 becomes thin, the rigidity of a tip part cannot fully be lowered at the time of insertion in a blood vessel.

[0011]When the narrow segment which this invention was made in view of such the actual condition, and was formed in the abdominal cavities, such as a blood vessel, is narrow, Even when [which is carrying out eccentricity], and it case or moves in a zigzag direction, the catheter tip is flexibly thin enough, It aims at providing a balloon catheter for abdominal cavity extension which it is [balloon catheter] possible to advance balloon membrane of a balloon catheter easily and correctly to the narrow segment position of the abdominal cavity, and can demonstrate the abdominal cavity expanded function of a balloon catheter effectively, and a manufacturing method for the same.

[Translation done.]

MEANS

[Means for Solving the Problem]To achieve the above objects, the 1st balloon catheter for abdominal cavity extension concerning this invention, It is a balloon catheter for abdominal cavity extension which has the tubed balloon membrane which widens a channel in the abdominal cavity by being inserted into the abdominal cavities, such as a blood vessel, and expanding, An outer diameter of a tip part of said tubed balloon membrane and an outer diameter of a center section are made into R_s and R_l, respectively, When thickness of a tip part of said tubed balloon membrane and a center section is made into t_s and t_l, respectively, relation between these R_s, R_l, t_s, and t_l satisfies following the (1) type.
[0013]
[Equation 2]
$R_l x t_l - t_l^2 >= 0.9x\ (R_s x t_s - t_s^2)$ .... (1)
A manufacturing method of the 1st balloon catheter for abdominal cavity extension concerning this invention, To thickness in both ends, blow molding of a process which thickness in a center section prepares tube shape thick parison, and this parison is carried out, and it has the process of forming balloon membrane which has a tubed balloon membrane center section where an outer diameter is large, and a tubed tip part and a base end where an outer diameter located in those both ends is small.
[0014]As a method for thickness in a center section to prepare tube shape thick parison to thickness in both ends, a method of carrying out light-gage processing of the both ends of parison of uniform thickness is in shaft orientations before blow molding of parison. A means which heats both ends of parison and it lets pass to a forming die as a means of light-gage processing, and a means to cut both ends of parison by machining can be illustrated. Cutting is easy to work and it is preferred from the ability to carry out light-gage processing of the both ends of parison certainly.
[0015]As the method of others for thickness in a center section to prepare tube shape thick parison to thickness in both ends, a method of equipping a center-section periphery of the 1st parison of uniform thickness with the 2nd parison with a large outer diameter whose shaft-orientations length is shorter than the 1st parison is in shaft orientations.
[0016]After carrying out blow molding of the parison of shaft-orientations uniform thickness and fabricating balloon membrane as an option for manufacturing the 1st balloon catheter for abdominal cavity extension concerning this invention, a method of making thickness of a tip part of balloon membrane thin is by cutting the tip part at least.
[0017]The 2nd balloon catheter for abdominal cavity extension of this invention, Balloon membrane which widens a channel in the abdominal cavity by being inserted into the abdominal cavities, such as a blood vessel, and expanding, A catheter tube with which the 1st lumen that a tip is connected to a end face of this balloon membrane, introduces a fluid into an inside of the

balloon membrane concerned, and swells balloon membrane is formed, Have formed an open end in a tip part and a tip part of said balloon membrane is connected to a periphery of the tip part, It is a balloon catheter for abdominal cavity extension which has the inner tube with which said balloon part and an inside of a catheter tube are extended in shaft orientations, and the 2nd lumen is formed, The diameter of an outer diameter of a tip part of an inner tube to which a tip part of said balloon membrane is connected is reduced smaller than an outer diameter of an inner tube located in a center section of balloon membrane.

[0018]As a means for reducing small only the diameter of an outer diameter of a tip part of an inner tube, a means which it lets pass to a forming die, and a means to cut by machining are employable, heating a tip part of an inner tube. A tip part of balloon membrane is connected to a tip part of an inner tube whose diameter was reduced by adhesion, thermal melting arrival, or other means.

[0019]A balloon catheter for abdominal cavity extension is preferably used for percutaneous transluminal coronary angioplasty (PTCA).

[0020]

[Translation done.]

OPERATION

[Function]The thickness of the tip part of balloon membrane is designed thinly it be satisfied with the 1st balloon catheter for abdominal cavity extension concerning this invention of the above-mentioned (1) formula. The tip part thickness of balloon membrane was fabricated in the conventional example thickly more than needed, in order to secure the thickness of the center section of the balloon membrane after blow molding. In this invention, it becomes possible to fabricate the tip part thickness of balloon membrane thinly, without reducing pressure-proofing of the balloon membrane in a balloon membrane center section by adopting the manufacturing method of above-mentioned this invention.
[0021]If the thickness of the tip part of balloon membrane becomes thin, the outer diameter of the tip part of a balloon catheter will also become small, A narrow narrow segment, a strong narrow segment, or a hard narrow segment can also push a balloon catheter along with a guidewire easily, and can locate balloon membrane correctly in a narrow segment.
[0022]In the 2nd balloon catheter for abdominal cavity extension concerning this invention, since only the diameter of the outer diameter of the tip part of an inner tube is reduced small and adhesion or thermal melting arrival of the tip part of balloon membrane has been carried out to the portion, the outer diameter of the tip part of a balloon catheter becomes still smaller. The tip end part of an inner tube becomes thin meat, and the pliability of the portion improves. As a result, in the balloon catheter of this invention, even if it is the narrow segment which carried out eccentricity to the blood vessel, or the winding narrow segment, when the tip of a balloon catheter bends flexibly, along with a guidewire, it can push good.

[Translation done.]

EXAMPLE

[Example]Hereafter, the balloon catheter for abdominal cavity extension concerning this invention is explained in detail based on the example shown in a drawing.
The balloon catheter 2 concerning this example shown in 1st example drawing 1 is used for methods, such as an extended way of blood vessels, such as percutaneous transluminal coronary angioplasty (PTCA) and the limbs, an extended way of a top ureter, and a renal vasodilatation way, for example, and it is used in order to extend the narrow segment formed in a blood vessel or the other abdominal cavities. The following explanation explains as an example the case where the balloon catheter 2 of this example is used for PTCA.
[0024]The balloon catheter 2 for extension of this example has the balloon membrane 4, the catheter tube 6, the tee 8, and the inner tube 10. The base end 5 of the balloon membrane 4 is connected to the tip part of the catheter tube 6, and the tee 8 is connected to the base end of the catheter tube 6.
[0025]The tip part 7 of this balloon membrane 4 is connected to the tip part periphery of the inner tube 10. Connection between the balloon membrane 4 and the inner tube 10 and connection between the balloon membrane 4 and the catheter tube 6 are made by join means, such as thermal melting arrival or adhesion. In order to insert a guidewire etc. in the inside of the inner tube 10, 12 [lumen / 2nd] is formed. The inner tube 10 is prolonged in shaft orientations in the state of the abbreviated same axle in the inside of the balloon membrane 4, the catheter tube 6, and the tee 8. Inside the catheter tube 6, 14 [lumen / 1st] is formed between the catheter tube 6 and the inner tube 10. The expansional port 16 currently formed in the tee 8 is open for free passage, and from there, a pressure fluid is introduced into 14 and swells the 1st lumen of the folded-up balloon membrane 4 to it.
[0026]Especially as a pressure fluid introduced in 1st lumen 14 through the expansional port 16, although not limited, 50/50 mixed water solution of radiopaque dye and salts, etc. are used, for example. It is for using radiation and imaging the position of the balloon membrane 4 and the catheter tube 6 at the time of use of the balloon catheter 2, to include radiopaque dye. Although the pressure in particular of the pressure fluid for swelling the balloon membrane 4 is not limited, it is about 4-8 atmospheres preferably 3-12 atmospheres in absolute pressure.
[0027]Along with the axial center of the inner tube 10, the guide port 18 is formed in the tee 8 separately [the expansional port 16]. The base end side open end of the inner tube 10 is connected to the tee 8 so that this guide port 18 may be open for free passage in the 2nd lumen 12 currently formed in the inner tube 10. Connection between the catheter tube 6 and the tee 8 and connection between the inner tube 10 and the tee 8 are made by thermal melting arrival, adhesion, or other means.
[0028]As for the catheter tube 6, it is preferred to comprise construction material which has a certain amount of flexibility, For example, polyethylene, polyethylene terephthalate, polypropylene, Ethylene propylene rubber, an ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), A

constructed type ethylene-vinylacetate copolymer of a bridge, polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and it comprises polyethylene, polyamide, and polyimide preferably. Although homogeneity may be sufficient as the outer diameter of the catheter tube 6, it is small to shaft orientations at a balloon membrane 4 close-attendants side, and it may form a step or a taper part in them on the way so that it may become large in other portions. By enlarging the 1st lumen of the passage cross section of 14, it is for shortening the time which shrinks the balloon membrane 4. After the balloon membrane 4 expands about 1 minute, it is because it is required to make it contract immediately, and is for securing the blood flow by the side of a tip.

[0029]As for the outer diameter of the catheter tube 6, near the terminal area with the balloon membrane 4, about 0.6-1.0 mm is preferred, and its about 0.8-1.2 mm is preferred in the tee 8 side. As for the thickness of the catheter tube 6, about 0.05-0.15 mm is preferred. The inner tube 10 may comprise the same construction material as the catheter tube 6, for example, and comprises polyethylene, polyamide, and polyimide preferably. As a reinforcing member, stainless lines, a nickel titanium alloy line, etc. may be used. Especially if the inside diameter of this inner tube 10 is a path which can insert in a guidewire, it will not be limited, for example, it is 0.25-0.60 mm preferably 0.15-1.00 mm. As for the thickness of this inner tube 10, 0.05-0.15 mm is preferred. Although the overall length of the inner tube 10 is determined according to the shaft-orientations length etc. of the balloon catheter 2 inserted into a blood vessel and is not limited in particular, it is about 130-140 mm preferably 120-150 mm, for example. The open end 20 is formed in the tip part of the inner tube 10. It is possible to draw the guidewire which inserted in the inside of 2nd lumen 12 of the inner tube 10 from this open end 20.

[0030]The circumference of the inner tube 10 located in the balloon membrane 4 can also be equipped with a radiopacity marker at one place or two or more places. As this marker, it can be with a metal tube, a metal spring, etc. which comprise gold, platinum, tungsten, iridium, or these alloys, for example. By attaching this marker to the circumference of the inner tube 10 in balloon membrane, the length of the position of the balloon membrane 4 or the extension of a balloon is detectable under the radioscopy at the time of use of the balloon catheter 2.

[0031]The tee 8 is suitably fabricated, for example with thermoplastics, such as polycarbonate, polyamide, poly SARUHON, polyacrylate, and a methacrylate butylene-styrene copolymer. The tubed balloon membrane center section 22 where the balloon membrane 4 has uniform outer diameter R_l (at the time of balloon membrane expansion) in shaft orientations in this example as shown in drawing 1 and 2, It is provided in the both ends and has the tubed tip part 7 and the base end 5 which have outer diameter R_s smaller than the balloon membrane center section 22 and R_s', respectively. The tip part 7 and the base end 5, and the balloon membrane center section 22 are continuously fabricated by the taper parts 24 and 26 which have reduced the diameter of an outer diameter to shaft orientations at ****.

[0032]Although thickness t_l in particular in the balloon membrane center section 22 of the balloon membrane 4 is not limited, about tens of micrometers are preferably preferred 15-200 micrometers. As long as the balloon membrane 4 is cylindrical, it may not be limited in particular but a cylinder or the shape of a multiple cartridge may have as it. Outer diameter R_l in the balloon membrane center section 22 of the balloon membrane 4 at the time of expansion is determined by factors, such as an inside diameter of a blood vessel, and its about 1.5-4.0 mm is preferred. Although shaft-orientations length L of the balloon membrane center section 22 of this balloon membrane 4 is determined by factors, such as a size of an intravascular narrow segment, and is not limited in particular, it is 20-40 mm preferably 15-50 mm. The balloon membrane 4 before expanding is folded up around the inner tube 10 shown in drawing 1, is twisted, and has become an outer diameter of the catheter tube 6, and below equivalent.

[0033]As for the construction material which constitutes the balloon membrane 4, it is preferred that it is the construction material which has a certain amount of flexibility, For example, polyethylene, polyethylene terephthalate, polypropylene, Ethylene propylene rubber, an ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), A constructed type ethylene-vinylacetate copolymer of a bridge, polyurethane, polyamide, a polyamide elastomer, polyimide, a polyimide elastomer, silicone rubber, crude rubber, etc. can be used, and they are polyethylene, polyethylene terephthalate, and polyamide preferably.

[0034]As shown in drawing 2, in this example the outer diameter of the tip part 7 of the balloon membrane 4, and the outer diameter of the center section 22, Consider it as R_s and R_l, respectively, and the thickness of the tip part 7 of the balloon membrane 4, and the center section 22, When it is considered as t_s and t_l, respectively, the relation between these R_s, R_l, t_s, and t_l is set up satisfy following the (1) type. The method for manufacturing balloon membrane so that following the (1) type may be satisfied is mentioned later.

[0035]

[Equation 3]

$$R_l x t_l - t_l >= 0.9x\ (R_s x t_s - t_s^2) \text{ .... (1)}$$

In the balloon membrane of the conventional balloon catheter, from balloon membrane being manufactured by the usual blow molding, as shown in below-mentioned drawing 3, the relation of following the (2) type was suited.

[0036]

[Equation 4]

$$R_l x t_l - t_l^2 = R_s x t_s - t_s^2 \text{ .... (2)}$$

The meaning of the above-mentioned (2) formula is that the area (left side of the formula 2) of the film cross section in the center section 22 of the balloon membrane 4 is equal to the area (right-hand side of the formula 2) of the film cross section in the tip part 7 of the balloon membrane 4, for example in drawing 2. Since the conventional balloon membrane is fabricated by carrying out blow molding of the parison of shaft-orientations uniform thickness, the above-mentioned (2) formula is realized.

[0037]In this example, since the above-mentioned balloon membrane 4 was manufactured by adopting a process which is mentioned later, thickness t_s of the tip part 7 of the balloon membrane 4 was able to be made thin so that the above-mentioned (1) formula might be satisfied. Also about thickness t_s' of the base end 5 of the balloon membrane 4, it can fabricate in this example thinly so that following the (3) type may be satisfied.

[0038]

[Equation 5]

$$R_l x t_l - t_l^2 >= 0.9x\ (R_s' x t_s' - t_s'^{\,2}) \text{ .... (3)}$$

Next, the manufacturing method of the balloon membrane 4 shown in drawing 2 is explained. First, as shown in drawing 3 (A), thickness and outer diameter R_0 prepares the tube shape uniform parison 4a in shaft orientations. Although outer diameter R_0 in particular of the parison 4a is not limited, it is 0.5-1.5 mm preferably 0.2-2.0 mm. Although the thickness in particular of the parison 4a is not limited, it is 0.3-0.7 mm preferably 0.2-0.9 mm. Although length L_0 in particular of the parison 4a is not limited, it is 20-300 mm preferably 10-500 mm.

[0039]Next, as shown in drawing 3 (B), light-gage processing of the both ends 5a and 7a of the parison 4a is carried out. The method of heating the both ends 5a and 7a of the parison 4a, and letting it pass to a forming die as the method of light-gage processing, and the method of cutting the both ends 5a and 7a of the parison 4a by machining can be illustrated. In the method of

letting it pass to a forming die, the inside diameter of the parison 4a does not change by using a mandrel. Cutting is easy to work and it is preferred from the ability to carry out light-gage processing of the both ends of parison certainly.
[0040]The outer diameter of the both ends 5a and 7a after light-gage processing is 0.4-1.2 mm preferably 0.2-1.6 mm. The thickness is 100 to 300% preferably 50 to 400% to the thickness in a parison center section.
Specifically, it is 0.1-0.3 mm preferably 0.05-0.40 mm.
Length range L_1 of the both ends 5a and 7a by which light-gage processing is carried out is 2-50 mm preferably 1-100 mm.
[0041]Then, while these both ends equip with the parison by which light-gage processing was carried out in a blow molding public-funds type and heat it, pressure gas or a pressure liquid is poured inside the parison 4a, blow molding is performed, and the balloon membrane 4 of shape as shown in drawing 2 is formed. Next, how to perform a PTCA therapy is explained using the balloon catheter 2 of the example shown in drawing 1.
[0042]First, the air in the balloon catheter 2 is removed as much as possible. then, the guide port 18 of the tee 8 to the inside of the inner tube 10 -- the 2nd lumen of fluids, such as a physiological saline, are put into 12, and the air in 2nd lumen 12 is replaced. To the expansional port of the tee 8, suction and injection means, such as a syringe, are attached, fluids, such as a blood contrast medium (for example, iodine content), are put in in a syringe, suction and pouring are repeated, and the air in 1st lumen 14 and the balloon membrane 4 is replaced by a fluid at it.
[0043]In order to insert the balloon catheter 2 into an arterial blood pipe, the guidewire for guide catheters (not shown) is first inserted into a blood vessel by Seldinger method etc. so that the tip may arrive to near the heart. Then, along with the guidewire for guide catheters, the guide catheter 32 shown in drawing 4 is inserted into the arterial blood pipe 34, and the tip is located in the coronary artery entrance 40 of the heart 38 which has the narrow segment 36. The narrow segment 36 is formed, for example of a thrombus or arteriosclerosis.
[0044]Next, only the guidewire for guide catheters is sampled, the guidewire 42 for balloon catheters thinner than it is inserted along with the guide catheter 32, and the tip is inserted to the position which passes the narrow segment 36. Then, the end face of the guidewire 42 shown in drawing 4 is inserted in the open end 20 of the balloon catheter 2 shown in drawing 1, and where through and the balloon membrane 4 are folded up in 2nd lumen 12 of the inner tube 10, it lets the balloon catheter 2 pass in the guide catheter 32 shown in drawing 4. And the balloon membrane 4 of the balloon catheter 2 is inserted to this side of the narrow segment 36, as shown in drawing 4. Or after extracting the guidewire for guide catheters from the guide catheter 32, The balloon catheter which inserted in the guidewire in 2nd lumen 12 of an inner tube from the guide port 18 of the tee may be inserted from the base of the guide catheter shown in drawing 4, the balloon membrane 4 may be drawn in a coronary artery, and the tip of the guidewire 42 may also be inserted to the position which passes the narrow segment 36.
[0045]Then, as shown in drawing 5 (A), the tip part 7 of the balloon membrane formed in the tip of the balloon catheter 2 is inserted between the narrow segments 36 along with the guidewire 42. In that case, the thickness of the tip part 7 of the balloon membrane 4 from a thin thing by this example. When the outer diameter is small and the gap of the guidewire 42 and the narrow segment 36 is small, as shown in drawing 5 (B) and (C), the balloon catheter 2 can be easily pushed also by the strong narrow segment or a hard narrow segment. Since the reaction force generated when pushing the balloon catheter 2 in the narrow segment 36 is received when the tip side bending part 44 of the guide catheter 32 shown in drawing 4 contacts the wall of the blood vessel 34, it is preferred that this reaction force is small. In this example, this reaction force becomes small.
[0046]Next, the balloon membrane 4 is correctly located in the center section of the narrow segment 36, observing the position of the balloon membrane 4 with an X-ray fluoroscope etc., as

shown in drawing 5 (C). By swelling the balloon membrane 4 in the position, the narrow segment 36 of the blood vessel 34 can be extended, and a good therapy can be performed. In order to swell the balloon membrane 4, it lets 14 [lumen / 1st] pass from the expansional port 16 shown in drawing 1, and carries out by pouring in fluids, such as a contrast medium, into the balloon membrane 4.

[0047]Although this expansion time in particular is not limited, it is a for [about 1 minute] grade, for example. Then, a fluid is promptly drained from the balloon membrane 4, balloon membrane is shrunk, and the blood flow by the side of the tip of the extended narrow segment 36 is secured. To the same narrow segment 36, although expansion of the balloon membrane 4 is 1 time, depending on the conditions of the narrow segment 36, multiple times may usually be sufficient as it.

[0048]Next, other examples of this invention are described.

2nd example this example is related with the manufacturing method of others of the balloon membrane 4 shown in drawing 2. Since it is the same as that of the 1st example of the above except the manufacturing method of the balloon membrane 4, the explanation is omitted.

[0049]In this example, as shown in drawing 6, the parison 4b by which the diameter of both ends was reduced is prepared by equipping the center-section periphery of the 1st parison 28 with the 2nd parison 30, and carrying out adhesion or thermal melting arrival of these to it. The parison 4b has as a result the parison 4a and the identical size which are shown in drawing 3 (B).

[0050]After that, the balloon membrane 4 shown in drawing 2 can be formed like the 1st example.

In 3rd example this example, after manufacturing balloon membrane by the same method as usual, those light-gage processings are performed by the method of letting it pass to a forming die, heating the tubed tip part and tubed base end of the method of carrying out machinery cutting of the periphery of the tubed tip part of balloon membrane, and a tubed base end, or balloon membrane. The balloon membrane 4 shown in drawing 2 concerning the 1st example of the above also by such a method can be manufactured.

[0051]Other processes and structures are the same as that of the 1st example of the above. As compared with the balloon catheter 2 of the example shown in drawing 1, it is that the joining structure of the balloon membrane 4A, the inner tubes 10A, and these tip parts is only different, and the other composition of the balloon catheter 2A concerning the example shown in 4th example drawing 7 is the same. So, identical codes are given to the member which is common in the balloon catheter 2 of the example shown in drawing 1, and a part of the explanation is omitted to it. It is the same as that of the 1st example of the above except describing to below specially about construction material, a size, etc. of the balloon membrane 4A and the inner tube 10A.

[0052]As for the balloon membrane 4A, in the balloon catheter 2A of this example, it is preferred that the tip part 7b and base end 5b fabricate thinly like the balloon membrane shown in drawing 2 compared with the former so that the above-mentioned (1) formula and (2) types may be satisfied. However, in this example, since the portion is not the point, the same thickness as usual may be sufficient as the tip part 7b and the base end 5b of the balloon membrane 4A.

[0053]In this example, as shown in drawing 8 (A) and (B), as compared with the outer diameter of other portions (inner tube 10A located in the center section of the balloon membrane 4A shown in drawing 7), the diameter of the outer diameter of the tip part 70 of the inner tube 10A is reduced small. As for the inside diameter of the inner tube 10A, since a guidewire is inserted in, it is preferred to shaft orientations that it is approximately regulated. Therefore, in the tip part 70 of the inner tube 10A, the thickness becomes thinner than other portions.

[0054]The inside diameter of the inner tube 10A is 0.25-0.60 mm preferably 0.15-1.00 mm like the case of said 1st example, for example. The thickness of inner tubes 10A other than tip part 70 is 0.05-0.15 mm.

30 to 70% of the thickness in the tip part 70 is desirable to thickness other than this tip part 70, and, specifically, its 0.05-0.10 mm is preferred.

[0055]As for length L_2 of the tip part 70 in the inner tube 10A whose diameter was reduced, it is preferred that they are the length equivalent to a terminal area with the tip part 7b of the balloon membrane 4A shown in drawing 1 or length longer than it, and, specifically, its 2-20 mm is preferred. A drawing stretching process or an extrusion stretching process using mechanical cutting or the forming die, and the mandrel as a means for reducing the diameter of the tip part 70 of the inner tube 10A etc. can be used.

[0056]In the balloon catheter 2A concerning this example, since only the diameter of the outer diameter of the tip part 70 of the inner tube 10A is reduced small and adhesion or thermal melting arrival of the tip part 7b of the balloon membrane 4A has been carried out to the portion, the outer diameter of the tip part of the balloon catheter 2A becomes small. The tip part 70 of the inner tube 10A becomes thin meat, and the pliability of the portion improves. As a result, in the balloon catheter 2A of this example, even if it is the narrow segment which carried out eccentricity to the blood vessel, or the winding narrow segment, when the tip of the balloon catheter 2A bends flexibly, along with a guidewire, it can push good.

[0057]this invention is not limited to the example mentioned above, within the limits of this invention, can be boiled variously and can be changed. For example, although each above-mentioned example explained as an example the case where the balloon catheter concerning this invention was used for a PTCA cure, the balloon catheter concerning this invention can be widely used, in order to extend the abdominal cavity of the blood vessel or others in which the narrow segment etc. were formed.

[0058]Next, although this invention is explained still more concretely, this invention is not limited to these examples.

The balloon was fabricated using the tube of Example 1 and comparative example 1 Nylon 11.

[0059]The line elastic moduli of used Nylon 11 were about 4500 kg/cm. As shown in drawing 10, perform machinery cutting of both ends, and R_l 1.125 mm, R_s=R_s' prepared the tube before balloon shaping of the size whose Lc of 0.374 mm and t_l 40 mm and Lb are 30 mm and 0.4 mm and La is [1.072 mm and R_d / 0.325 mm and t_s'=t_s] 20 mm.

[0060]This tube was put into the mold, heat pressing was performed for about 10 seconds by 184 ** and 7 kg/cm^2, and balloon membrane was fabricated. The tip part and the hand part were cut after shaping using the cutting machine. The balloon membrane (example 1) after cutting is 3 mm in outer diameter of a center section, and is 0.1 mm in thickness.

The outer diameter of the tip part was set to 1.2 mm, and thickness was set to 0.30 mm.

The size of the hand part was 0.23 mm in 1.36 mm and thickness in the outer diameter. Except not cutting both ends after the heat pressing within a mold, like the above-mentioned, the size of the balloon membrane (comparative example 1) after shaping was 1.42 mm in the outer diameter of 0.42 mm and a hand part, was 1.60 mm in thickness, and was [the outer diameter of the tip part] 0.35 mm in thickness.

[0061]Two kinds of this balloon membrane (Example 1 and the comparative example 1) was connected to the catheter tube which consists of the outer tube and inner tube made from polyethylene, respectively. The line elastic coefficients of the used polyethylene were about 1000 kg/cm. The inner-tube tube which connected the tip part of balloon membrane is a with the outer diameter of 0.6 mm, and a thickness of 0.08 mm thing.

The outer-tube tube which connected the hand end part was a with the outer diameter of 0.9 mm, and a thickness of 0.08 mm thing.

Elastic polyurethane rubbers were used as adhesives. In this example, it is $R_l x t_l - t_l^2$=0.29, It is 0.9

$(R_s x t_s - t_s^2)$= 0.243, and is a formula. $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied.

[0062]On the other hand, it is $R_l x t_l - t_l^2 = 0.29$, and is $0.9(R_s x t_s - t_s^2)$= 0.378, and the above-mentioned (1) formula is not filled with the comparative example 1. Next, it bent to 2.5 mm in inside diameter and the curvature radius of 10 mm which were immersed into warm water, and the experiment which inserts in the balloon catheter of Example 1 and the comparative example 1 in the hard tube made from polyvinyl chloride which imitated and created the blood vessel was conducted.

[0063]The result tried 10 times respectively is shown.

[0064]

[Table 1]

	挿通した	挿通せず
(両端加工例) 実施例 1	8	2
(両端未加工例) 比較例 1	3	7

[0065]As shown in the above-mentioned table, this difference originates in the size, especially tip thickness at the tip of a balloon. Although the thickness difference near a tip is slight, when it is made to insert in by Example 1 and the comparative example 1 in the hard tube which imitated the curvature radius of 10 mm, and the blood vessel distorted strongly, in this example, the rigidity at the tip of a catheter becomes low on structural mechanics.

[0066]Under the conditions to which transfer of the power pushed in with a soft catheter tube is restricted, it is thought according to this example 1 and the comparative example 1 that the difference arose in the ease of inserting in. In clinical [actual], since the blood vessel inside diameter is also ****(ed) remarkably, then, it is considered to work in favor of the insertion nature of a catheter that the balloon tip outer diameter by this example is also small.

[0067]R_l in the tube shown in example 2 drawing 10 1.125 mm, R_d created the tube of Nylon 11 of the size which 0.346 mm calls 1.017 mm in 0.325 mm and $t_s = t_s'$, and 0.4 mm and $R_s = R_s'$ say in t_l. Using this tube, balloon membrane was fabricated like Example 1 and post forming both ends were cut. The outer diameter by the side of the tip part of a balloon, a center section, and a hand part and thickness were 1.13 mm (outer diameter)/0.27 mm (thick), 3.00 mm (outer diameter)/0.10 mm (thick), and 1.32 mm (outer diameter)/0.21 mm (thick) respectively. In this example, it is $R_l x t_l - t_l^2 = 2.9$, it is $0.9(R_s x t_s - t_s^2)$= 0.20897 -- formula $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied. This balloon membrane was connected to the catheter shown in Example 1, and insertion in the imitation blood vessel shown in Example 1 was tried 10 times. A result is shown in Table 2.

[0068]

[Table 2]

	挿通した	挿通せず
実施例 2	1 0	0

[0069]The tube of Nylon 11 as shown in Examples 3 and 4 and two or less comparative example was prepared, and balloon membrane was fabricated. The line elastic coefficients of used Nylon 11 were about 4500 kg/cm. The tube of Examples 3 and 4 cut both ends mechanically, as

illustrated to drawing 10, and it made them the predetermined outer diameter.
[0070]After having put these tubes into the mold, carrying out heat pressing like Example 1 and fabricating a balloon, using the cutting machine, the tip part and the hand part were cut and it was considered as a predetermined outer diameter and thickness. Any balloon membrane of the thickness in 3.0 mm and the portion of those of the outer diameter of the balloon center section was 0.16 mm.
[0071]The tube dimensions for fabricating the balloon membrane of Example 3, 0.325 mm and $t_s=t_s'$ are 0.374 mm and 1.073 mm and R_d is [R_l / t_l of 1.37 mm and $R_s=R_s'$] 0.53 mm in drawing 10. The outer diameter of the balloon center section of the balloon membrane after shaping is 3.0 mm, thickness is 0.16 mm, and they are 1.36 mm in outer diameter, and 0.23 mm in thickness in a tip part at the outer diameter of 1.20 mm, the thickness of 0.30 mm, and a hand part. In this example, it is $R_l x t_l - t_l^2 = 0.4544$, It is $0.9(R_s x t_s - t_s^2) = 0.243$, and is a formula. $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied. The tube dimensions for fabricating the balloon membrane of Example 4, 0.325 mm and $t_s = t_s'$ are 0.495 mm, and 1.31 mm and R_d is [R_l / t_l of 1.39 mm and $R_s=R_s'$] 0.53 mm in drawing 10. The outer diameter of the balloon center section of the balloon membrane after shaping is 3.0 mm, thickness is 0.16 mm, and they are 1.56 mm in outer diameter, and 0.33 mm in thickness in a tip part at the outer diameter of 1.41 mm, the thickness of 0.40 mm, and a hand part. In this example, it is $R_l x t_l - t_l^2 = 0.4544$, It is $0.9(R_s x t_s - t_s^2) = 0.3636$, and is a formula.
$R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied.
[0072]In the comparative example 2, it is made the same in Example 4 except not cutting both ends after the heat pressing within a mold, The outer diameter of the balloon center section fabricated 3.0 mm, and thickness fabricated with the outer diameter of 1.71 mm, and a thickness of 0.40 mm balloon membrane by the outer diameter of 1.57 mm, the thickness of 0.48 mm, and a hand part by 0.16 mm and a tip part.
[0073]In this comparative example, it is $R_l x t_l - t_l^2 = 0.4544$, It is $0.9(R_s x t_s - t_s^2) = 0.47088$, and is a formula. $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is not satisfied. These kinds of balloon membrane was connected to the catheter tube made from polyethylene like Example 1.
[0074]The line elastic coefficient of the used polyethylene was about 1000kg/cm. The outer-tube tube which connected the inner-tube tube linked to a balloon tip part to the outer diameter of 0.6 mm, the thing with a thickness of 0.08 mm, and the balloon hand end part was a with the outer diameter of 0.9 mm, and a thickness of 0.08 mm thing. Elastic polyurethane rubbers were used as adhesives.
[0075]Next, it bent to 2.5 mm in inside diameter and the curvature radius of 10 mm which were immersed into warm water, and the experiment which inserts in the balloon catheter of these examples and a comparative example in the hard tube made from polyvinyl chloride which imitated and made the blood vessel was conducted. Respectively, the result tried 10 times is shown in Table 3.
[0076]
[Table 3]

	挿通した	挿通せず
実施例 3	１０	0
実施例 4	8	2
比較例 2	2	8

[0077]As shown in Table 3, the difference large in the insertion characteristic was seen by the example and the comparative example. This difference originates in the size at the tip of a balloon, especially thickness. Although the thickness difference near a tip is only 0.08 mm, when it is made to insert in in an example and a comparative example in the hard tube which imitated the curvature radius of 10 mm, and the blood vessel distorted strongly, in this example, the rigidity at the tip of a catheter is low.
[0078]Under these conditions to which transfer of the power pushed in with a soft catheter tube is restricted, it is thought that the direction of Example 4 produced the difference in the ease of inserting in compared with the comparative example. It is based on the same reason that especially Example 3 was excellent. In clinical [actual], since the blood vessel inside diameter is also ****(ed) remarkably, it is then considered to work in favor of the insertion nature of a catheter that the balloon tip outer diameter by this example is also small.
[0079]R_l shown in drawing 10 by the method of letting a tube pass to Example 5 and the die heated comparative example 3 1.125 mm, R_s'=R_s created the tube of Nylon 11 whose t_l 0.325 mm and t_s=t_s' are 0.346 mm and 1.017 mm and R_d is 0.4 mm.
[0080]After carrying out heat pressure molding with a metallic mold like Example 1 using this tube, the tip part and the hand part were cut with the cutting machine, and balloon membrane was created. The outer diameter by the side of the tip part of balloon membrane, a center section, and a hand part and thickness were respectively set to 1.13 mm (outer diameter)/0.27 mm (thick), 3.00 mm (outer diameter)/0.10 mm (thick), and 1.32 mm (outer diameter)/0.21 mm (thick). In this example, it is $R_l x t_l - t_l^2$=0.29, it is $0.9(R_s x t_s - t_s^2)$= 0.209 -- formula $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is satisfied. The catheter tube made from polyethylene shown in previous Examples 3 and 4 was connected to this.
[0081]The balloon membrane fabricated not reducing thickness of both ends as a comparative example (without it cuts) was similarly connected to said catheter tube made from polyethylene. An outer diameter and the thickness of the size of the tip part, the center section, and the hand part were 1.48 mm (outer diameter)/0.44 mm (thick), 3.00 mm (outer diameter)/0.10 mm (thick), and 1.64 mm (outer diameter)/0.37 mm (thick).
[0082]In a comparative example, it is $R_l x t_l - t_l^2$=0.29, it is $0.9(R_s x t_s - t_s^2)$= 0.412 -- formula $R_l x t_l - t_l^2 >= 0.9 (R_s x t_s - t_s^2)$ ... (1)
****** is not satisfied. Insertion in the imitation blood vessel which used these catheters in the example 3 grade was tried 10 times respectively. A result is shown in Table 4.
[0083]
[Table 4]

	挿通した	挿通せず
実施例 5	１０	0
比較例 3	3	7

[0084]Only the diameter of the tip part of a with example 6 outer diameter of 0.6 mm and a

thickness of 0.08 mm tube was reduced by cutting etc., it was made into the outer diameter of 0.52 mm, and the thickness of 0.04 mm (other portions the outer diameter of 0.6 mm, thickness of 0.08 mm), and the inner tube of the balloon catheter was fabricated.
[0085]Apart from this, R_l shown in drawing 10 like Example 4 1.39 mm, R_s=R_s' formed the tube whose t_l 0.325 mm and t_s=t_s' are 0.495 mm and 1.31 mm and R_d is 0.53 mm by cutting. After carrying out heat pressure molding of this tube within a metallic mold, cut it and The tip part of balloon membrane, The size of the center section and the hand part fabricated 1.37 mm (outer diameter)/0.43 mm (thick), 3.00 mm (outer diameter)/0.16 mm (thick), and 1.56 mm (outer diameter)/0.33 mm (thick) of balloon membrane.
[0086]This balloon membrane was connected to the inner tube (tube with which the tip part of the inner tube became thin) and outer tube (it is the same as Example 1) of said balloon catheter, the catheter was assembled like Example 1, and it examined by the same method as Example 1. A result is shown in Table 5.
[0087]
[Table 5]

	挿通した	挿通せず
実施例 6	9	1

[0088]In this example, the tip outer diameter of the balloon is thin 0.04 mm (about 3%) by having reduced the diameter of an inner-tube tube compared with Example 4. It is expected that this will have good insertion nature at the time of application in the blood vessel which ****(ed) in clinical [actual].

[Translation done.]

DESCRIPTION OF DRAWINGS

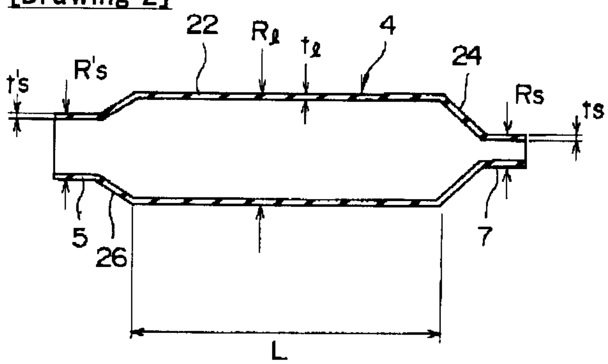
[Brief Description of the Drawings]
[Drawing 1]Drawing 1 is an outline sectional view of the balloon catheter concerning one example of this invention.
[Drawing 2]Drawing 2 is a sectional view of balloon membrane used for the balloon catheter shown in drawing 1.
[Drawing 3]Drawing 3 (A) and (B) is a perspective view showing the parison for manufacturing the balloon membrane shown in drawing 1.
[Drawing 4]Drawing 4 is a schematic diagram showing the directions for the balloon catheter shown in drawing 1.
[Drawing 5]Drawing 5 (A) - (C) is an important section sectional view showing the directions for the balloon catheter shown in drawing 1.
[Drawing 6]Drawing 6 is a sectional view of the parison for manufacturing the balloon membrane of the balloon catheter concerning other examples of this invention.
[Drawing 7]Drawing 7 is an outline sectional view of the balloon catheter concerning other examples of this invention.
[Drawing 8]Drawing 8 (A) and (B) is the important section perspective view and sectional view of a tip part of an inner tube which are shown in drawing 7.
[Drawing 9]Drawing 9 is a sectional view of balloon membrane used for the balloon catheter concerning a conventional example.
[Drawing 10]Drawing 10 is a perspective view showing the size of the parison for manufacturing the balloon membrane of the balloon catheter concerning the example and comparative example of this invention.
[Description of Notations]
2 2A -- Balloon catheter
4 4A -- Balloon membrane
5 5b -- Base end
6 -- Catheter tube
7 7b -- Tip part
8 -- Tee
10 10A -- Inner tube
12 -- The 2nd lumen
14 -- The 1st lumen
20 -- Open end
22 -- Balloon membrane center section
24, 26 -- Taper part
32 -- Guide catheter
34 -- Main artery

36 — Narrow segment

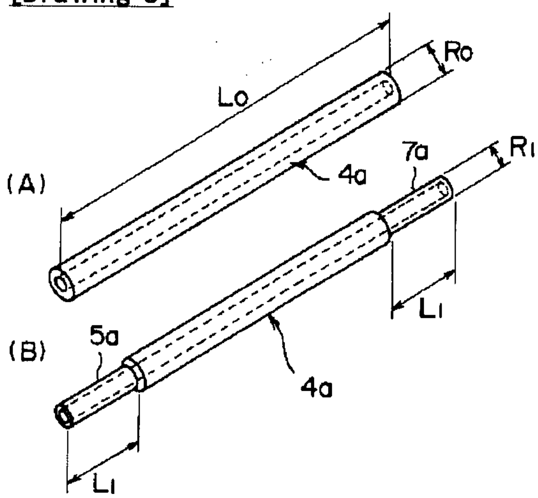
[Translation done.]

DRAWINGS

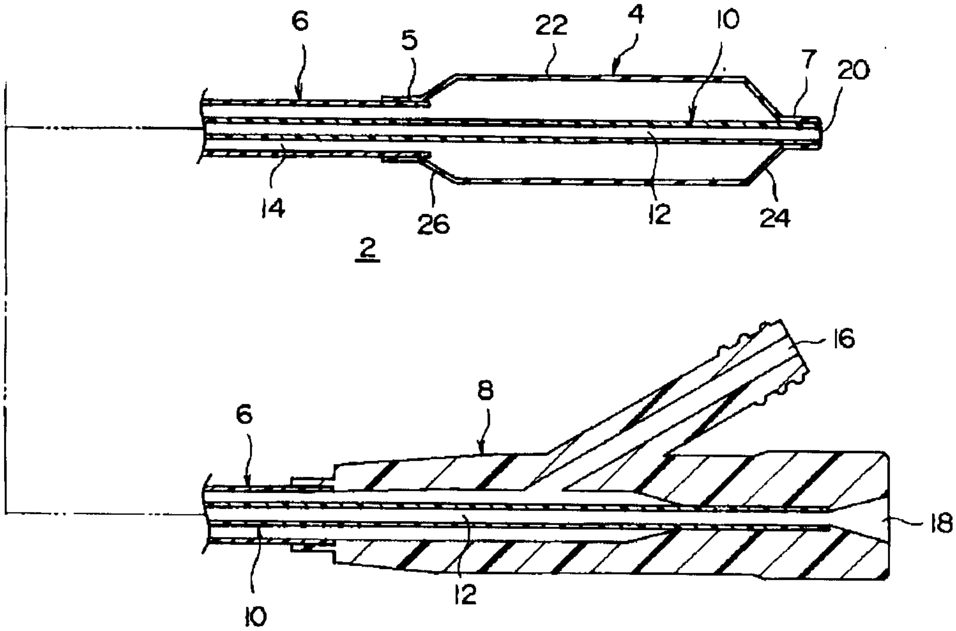
[Drawing 2]



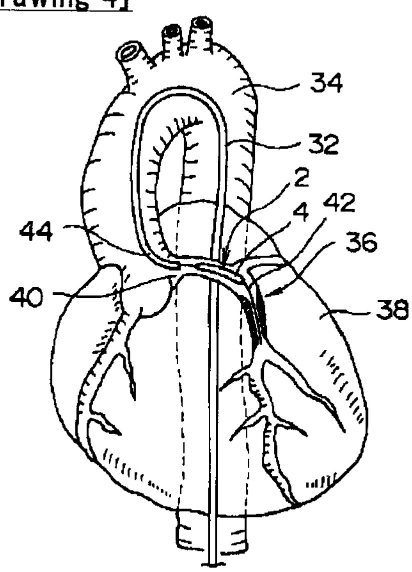
[Drawing 3]



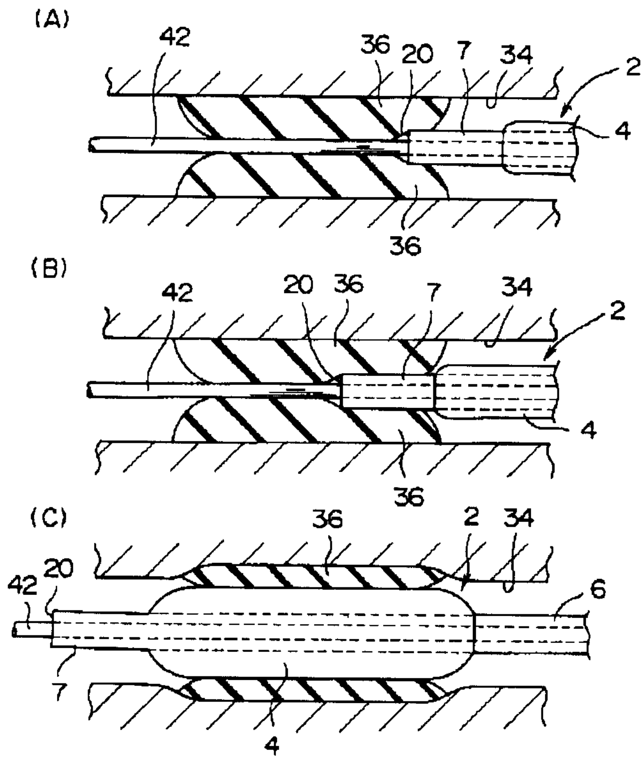
[Drawing 1]



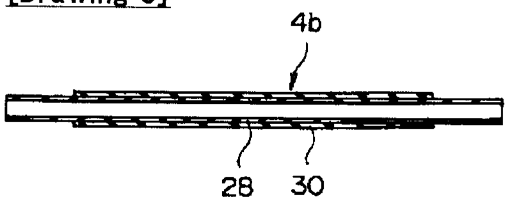
[Drawing 4]



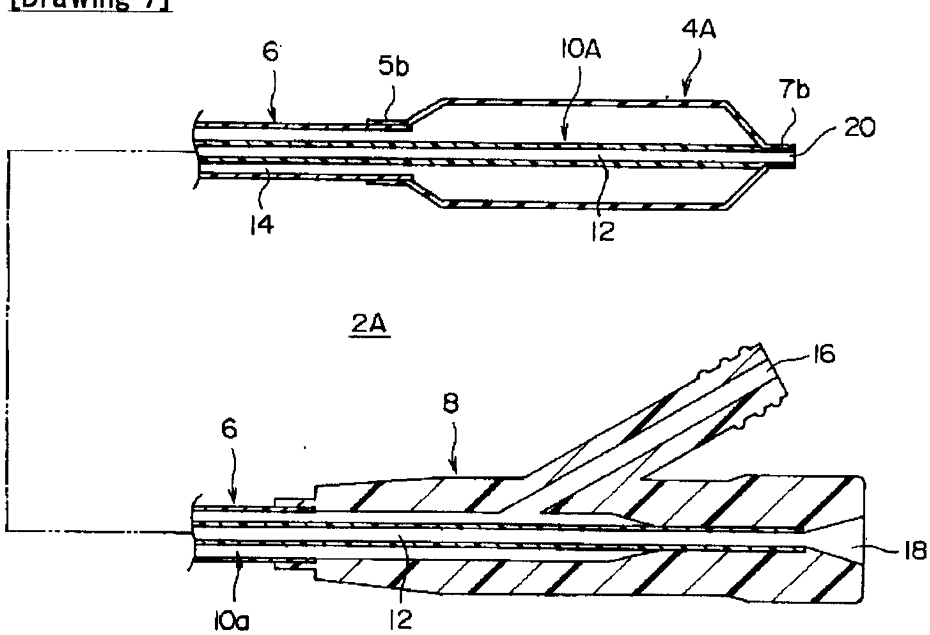
[Drawing 5]



[Drawing 6]

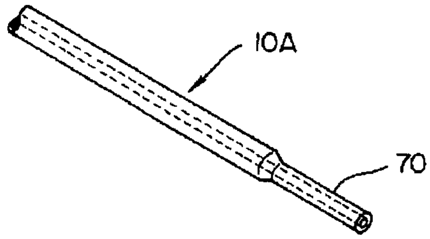


[Drawing 7]

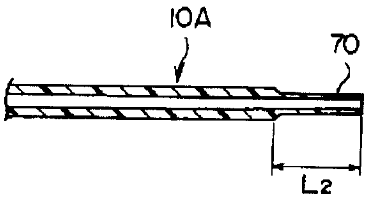


[Drawing 8]

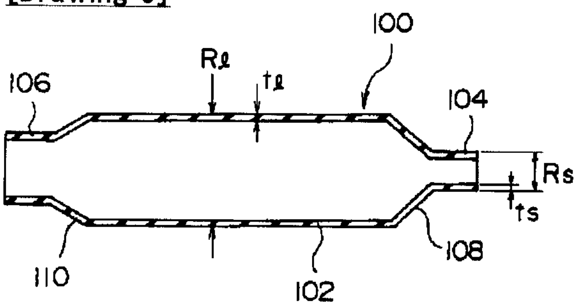
(A)



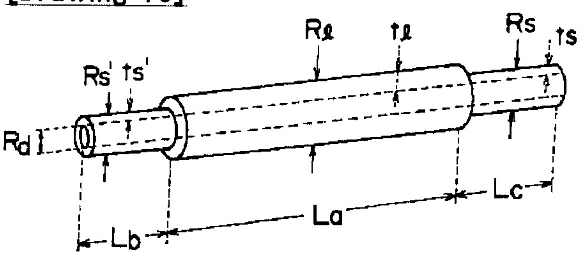
(B)



[Drawing 9]



[Drawing 10]



[Translation done.]

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(54)【発明の名称】　体腔拡張用バルーンカテーテルおよびその製造方法

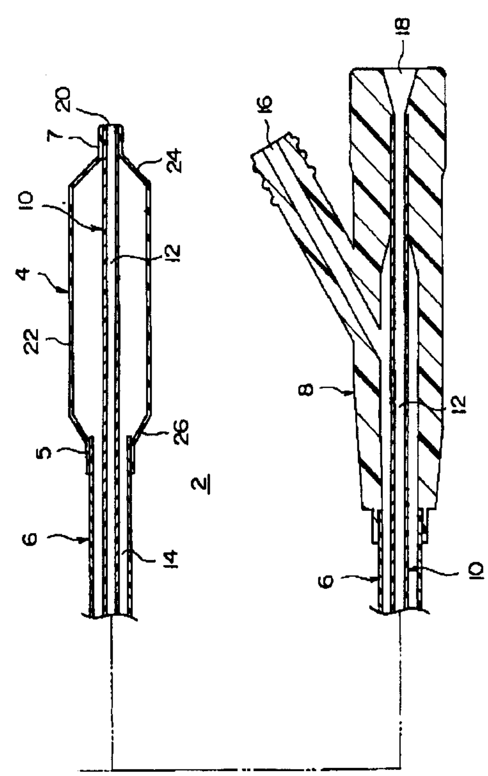
(57)【要約】

【目的】　血管などの体腔に形成された狭窄部が狭い場合、硬い場合、偏心している場合、あるいは蛇行している場合でも、バルーンカテーテルのバルーン膜を体腔の狭窄部位置まで容易にしかも正確に進めることが可能であり、バルーンカテーテルの体腔拡張機能を有効に発揮させることができる体腔拡張用バルーンカテーテルおよびその製造方法を提供すること。

【構成】　筒状のバルーン膜４の先端部７の外径および中央部２２の外径を、それぞれR_3およびR_1とし、筒状のバルーン膜４の先端部７および中央部２２の膜厚を、それぞれt_3およびt_1とした場合に、これらの関係が、下記（１）式を満足する。

$$R_1 \times t_1 - t_1{}^2 \geqq 0.9 \times (R_3 \times t_3 - t_3{}^2) \quad \cdots\cdots \quad (1)$$

この関係を満足するバルーン膜４を製造するには、まず、両端部での膜厚に対して、中央部での膜厚が厚いチューブ状のパリソンを準備する。その後、このパリソンをブロー成形する。



【特許請求の範囲】

【請求項1】　血管などの体腔内に挿入されて膨張することにより、体腔内流路を拡張する筒状のバルーン膜を有する体腔拡張用バルーンカテーテルであって、
前記筒状のバルーン膜の先端部の外径および中央部の外径を、それぞれR_sおよびR_1とし、前記筒状のバルー＊
＊ン膜の先端部および中央部の膜厚を、それぞれt_sおよびt_1とした場合に、これらR_s、R_1、t_sおよびt_1の関係が、下記（1）式を満足する体腔拡張用バルーンカテーテル。

【数1】

$$R_1 \times t_1 - t_1{}^2 \geqq 0.9 \times (R_s \times t_s - t_s{}^2) \quad \cdots\cdots \quad (1)$$

【請求項2】　両端部での膜厚に対して、中央部での膜厚が厚いチューブ状のパリソンを準備する工程と、
このパリソンをブロー成形し、外径が大きい筒状のバルーン膜中央部と、その両端に位置する外径が小さい筒状の先端部および基端部とを有するバルーン膜を形成する工程とを有する体腔拡張用バルーンカテーテルの製造方法。

【請求項3】　血管などの体腔内に挿入されて膨張することにより、体腔内流路を拡張するバルーン膜と、
このバルーン膜の基端に先端が接続され、当該バルーン膜の内部に流体を導入してバルーン部を膨らます第1ルーメンが形成してあるカテーテル管と、
先端部に開口端が形成してあり、その先端部の外周に前記バルーン膜の先端部が接続され、前記バルーン膜およびカテーテル管の内部を軸方向に延び、第2ルーメンが形成してある内管とを有する体腔拡張用バルーンカテーテルであって、
前記バルーン膜の先端部が接続される内管の先端部の外径が、バルーン膜の中央部に位置する内管の外径よりも小さく縮径してある体腔拡張用バルーンカテーテル。

【発明の詳細な説明】

【0001】

【産業上の利用分野】本発明は、血管などの体腔内に挿入されて膨張することにより、体腔内流路を拡張するバルーンカテーテルに係り、さらに詳しくは、たとえば血管内の狭窄部を治療するために、この狭窄部を拡張し、狭窄部抹梢側における血流の改善を図る用途に用いられる体腔拡張用バルーンカテーテルに関する。

【0002】

【従来の技術】血管内の狭窄部を治療するために、血管内に挿入し、バルーン膜を膨らますことにより狭窄部を拡張し、狭窄部抹梢側における血流の改善を図るためのバルーンカテーテルとして、ガイドワイヤーがカテーテルの基端部から挿通されるオーバー・ザ・ワイヤ型と、ガイドワイヤーがカテーテルの途中から外に出ているモノレール型のバルーンカテーテルが多く使用されている。これらのタイプのバルーンカテーテルでは、先にガイドワイヤを血管内狭窄部へ通過させておき、次にこのガイドワイヤに沿ってバルーンカテーテルを狭窄部まで送り込み、バルーン膜を膨らますことにより狭窄部を拡張する。

【0003】これらのタイプのバルーンカテーテルは、内部にガイドワイヤを挿通することができるルーメンが形成してある内管と、この内管に同軸的に装着されたカテーテル管と、先端部および基端部を有し、基端部がカテーテル管の先端部に取り付けられ、先端部が内管の先端部外周に取り付けられた折り畳み可能なバルーン膜とを有する。

【0004】これらのタイプのバルーンカテーテルは、操作性の点では、優れた効果を有している。これらのタイプのバルーンカテーテルにより、血管内の狭窄部を拡張し、狭窄部末端側の血流改善を図るためには、狭窄した血管内に前もって挿入されたガイドワイヤに沿ってカテーテルを前進させ、バルーン膜を血管の狭窄部に正確に位置させることが重要である。きわめて狭い狭窄部に、バルーンカテーテルの先端部を圧入していくので、このバルーンカテーテルの先端部は、できるだけ狭窄部に入り込み易いように外径が小さいことが好ましい。

【0005】

【発明が解決しようとする課題】しかしながら、従来のバルーンカテーテルでは、バルーン膜をブロー成形により成形しているため（たとえば特開平5－192408号公報、特公平2－28341号公報）、以下のような問題点を有している。すなわち、ブロー成形では、軸方向に均一な膜厚を有するチューブ状パリソンを加熱しつつ、その内部に圧力流体を導入することにより、パリソンを膨らまし、図9に示すような筒状のバルーン膜100を成形している。バルーン膜100は、バルーン膜中央部102で外径R_1が大きく、その先端部104および基端部106で外径R_sが小さくなるようになっている。先端部104および基端部106とバルーン膜中央部102との間には、テーパ部108，110が形成してある。

【0006】このようなバルーン膜100を、軸方向に均一肉厚のチューブ状パリソンから、ブロー成形で成形すれば、バルーン膜中央部102での膜厚t_1に対して、特に先端部104での膜厚t_sが厚くなる。バルーン膜中央部102と先端部104とでは、ブロー成形による伸び率が相違するからである。

【0007】先端部104の膜厚が厚いと、バルーンカテーテルの先端部の外径が大きくなると共に、先端部での剛性が高まる。その結果、バルーンカテーテルを、狭い狭窄部、硬い狭窄部、偏心した狭窄部あるいは蛇行した狭窄部などに対して、良好に押し進めることができ難い。

【0008】バルーンカテーテルのバルーン膜を正確に

狭窄部内に押し進めることができなければ、狭窄部を拡張して血流の改善を行うと言うバルーンカテーテル本来の機能を発揮できない。バルーン膜の先端部での膜厚を薄くするために、ブロー成形前のチューブ状パリソンの肉厚を薄くすることが考えられる。ところが、その場合には、ブロー成形後に、バルーン膜中央部での膜厚が薄く成りすぎ、耐圧が不十分になるおそれがある。バルーン膜は、患者の血管などの体腔内で膨張するように設計されるため、耐圧が不十分であってはならない。また、バルーン膜は、折り畳まれて患者の血管などの体腔内に挿入されるため、血管内への挿通が容易なように、できるだけ薄いことが好ましい。

【０００９】そこで、バルーン膜中央部の膜厚は、耐圧が十分である限界の薄さに設計する必要がある。そのため、チューブ状パリソンの肉厚は、バルーン膜中央部の設計膜厚に応じて決定され、バルーン膜１００の先端部１０４の膜厚が不必要に厚くなることは避けられなかった。

【００１０】なお、特開平４－１７６４７３号公報には、バルーン膜１００のテーパ部１０８，１１０の膜厚を薄くする目的で、ブロー成形後に、バルーン膜を軸方向に延伸加工し、テーパ部１０８，１１０の膜厚を薄くする技術が開示してある。しかしながら、ブロー成形後には、テーパ部１０８，１１０の膜厚変化を生じさせるほど延伸加工することは非常に困難である。また、仮に＊

＊テーパ部１０８，１１０の膜厚を変化させることができたとしても、先端部１０４の膜厚が薄くならない限り、血管への挿入時に先端部の剛性を十分に下げられない。

【００１１】本発明は、このような実状に鑑みてなされ、血管などの体腔に形成された狭窄部が狭い場合、硬い場合、偏心している場合、あるいは蛇行している場合でも、カテーテル先端が柔軟でかつ十分に細くなっていて、バルーンカテーテルのバルーン膜を体腔の狭窄部位置まで容易にしかも正確に進めることが可能であり、バルーンカテーテルの体腔拡張機能を有効に発揮させることができる体腔拡張用バルーンカテーテルおよびその製造方法を提供することを目的とする。

【００１２】

【課題を解決するための手段】上記目的を達成するために、本発明に係る第１の体腔拡張用バルーンカテーテルは、血管などの体腔内に挿入されて膨張することにより、体腔内流路を拡張する筒状のバルーン膜を有する体腔拡張用バルーンカテーテルであって、前記筒状のバルーン膜の先端部の外径および中央部の外径を、それぞれR_3およびR_1とし、前記筒状のバルーン膜の先端部および中央部の膜厚を、それぞれt_3およびt_1とした場合に、これらR_3、R_1、t_3およびt_1の関係が、下記（１）式を満足する。

【００１３】

【数２】

$$R_1 \times t_1 - t_1^2 \geqq 0.9 \times (R_3 \times t_3 - t_3^2) \quad \cdots\cdots \quad (1)$$

本発明に係る第１の体腔拡張用バルーンカテーテルの製造方法は、両端部での膜厚に対して、中央部での膜厚が厚いチューブ状のパリソンを準備する工程と、このパリソンをブロー成形し、外径が大きい筒状のバルーン膜中央部と、その両端に位置する外径が小さい筒状の先端部および基端部とを有するバルーン膜を形成する工程とを有する。

【００１４】両端部での膜厚に対して中央部での膜厚が厚いチューブ状のパリソンを準備するための方法としては、パリソンのブロー成形前に、軸方向に均一肉厚のパリソンの両端部を、薄肉加工する方法がある。薄肉加工の手段としては、パリソンの両端部を加熱して成形ダイに通す手段と、パリソンの両端部を機械加工により切削加工する手段とを例示することができる。切削加工は、作業が容易であると共に、確実にパリソンの両端部を薄肉加工することができることから好ましい。

【００１５】また、両端部での膜厚に対して中央部での膜厚が厚いチューブ状のパリソンを準備するためのその他の方法としては、軸方向に均一肉厚の第１パリソンの中央部外周に、その第１パリソンよりも軸方向長さが短く外径が大きい第２パリソンを装着する方法がある。

【００１６】本発明に係る第１の体腔拡張用バルーンカテーテルを製造するための別の方法としては、軸方向均一肉厚のパリソンをブロー成形してバルーン膜を成形した後に、少なくともその先端部を切削加工することにより、バルーン膜の先端部の膜厚を薄くする方法がある。

【００１７】本発明の第２の体腔拡張用バルーンカテーテルは、血管などの体腔内に挿入されて膨張することにより、体腔内流路を拡張するバルーン膜と、このバルーン膜の基端に先端が接続され、当該バルーン膜の内部に流体を導入してバルーン膜を膨らます第１ルーメンが形成してあるカテーテル管と、先端部に開口端が形成してあり、その先端部の外周に前記バルーン膜の先端部が接続され、前記バルーン部およびカテーテル管の内部を軸方向に延び、第２ルーメンが形成してある内管とを有する体腔拡張用バルーンカテーテルであって、前記バルーン膜の先端部が接続される内管の先端部の外径が、バルーン膜の中央部に位置する内管の外径よりも小さく縮径してある。

【００１８】内管の先端部の外径のみを小さく縮径するための手段としては、内管の先端部を加熱しつつ成形ダイに通す手段、機械加工により切削加工する手段を採用することができる。縮径された内管の先端部には、バルーン膜の先端部が、接着または熱融着などの手段で接続される。

【００１９】体腔拡張用バルーンカテーテルは、経皮的冠動脈形成術（ＰＴＣＡ）に好ましく用いられる。

【００２０】

【作用】本発明に係る第１の体腔拡張用バルーンカテーテルでは、上記（１）式を満足するように、バルーン膜の先端部の膜厚が、薄く設計されている。従来例では、バルーン膜の先端部膜厚は、ブロー成形後のバルーン膜の中央部の膜厚を確保するために、必要以上に厚く成形されていた。本発明では、上記本発明の製造方法を採用することにより、バルーン膜中央部でのバルーン膜の耐圧を低下させることなく、バルーン膜の先端部膜厚を薄く成形することが可能になる。

【００２１】バルーン膜の先端部の膜厚が薄くなれば、バルーンカテーテルの先端部の外径も小さくなり、狭い狭窄部、強い狭窄部、あるいは硬い狭窄部などでも、容易にバルーンカテーテルをガイドワイヤに沿って押し進めることができ、狭窄部内にバルーン膜を正確に位置させることができる。

【００２２】本発明に係る第２の体腔拡張用バルーンカテーテルでは、内管の先端部の外径のみを小さく縮径してあり、その部分にバルーン膜の先端部が接着または熱融着してあることから、バルーンカテーテルの先端部の外径がさらに小さくなる。また、内管の先端部分が薄肉になり、その部分の柔軟性が向上する。その結果、本発明のバルーンカテーテルでは、血管に対して偏心した狭窄部、あるいは蛇行した狭窄部であっても、バルーンカテーテルの先端が柔軟に曲折することにより、ガイドワイヤに沿って良好に押し進めることができる。

【００２３】

【実施例】以下、本発明に係る体腔拡張用バルーンカテーテルを、図面に示す実施例に基づき、詳細に説明する。

第１実施例

図１に示す本実施例に係るバルーンカテーテル２は、たとえば経皮的冠動脈形成術（ＰＴＣＡ）、四肢等の血管の拡張術、上部尿管の拡張術、腎血管拡張術などの方法に用いられ、血管あるいはその他の体腔に形成された狭窄部を拡張するために用いられる。以下の説明では、本実施例のバルーンカテーテル２をＰＴＣＡに用いる場合を例として説明する。

【００２４】本実施例の拡張用バルーンカテーテル２は、バルーン膜４と、カテーテル管６と、分岐部８と、内管１０とを有する。カテーテル管６の先端部には、バルーン膜４の基端部５が接続してあり、カテーテル管６の基端部には、分岐部８が接続してある。

【００２５】このバルーン膜４の先端部７は、内管１０の先端部外周に接続してある。バルーン膜４と内管１０との接続およびバルーン膜４とカテーテル管６との接続は、熱融着または接着などの接合手段で行われる。内管１０の内部には、ガイドワイヤなどを挿通するための第２ルーメン１２が形成してある。内管１０は、バルーン膜４、カテーテル管６および分岐部８の内部を略同軸状態で軸方向に延びている。カテーテル管６の内部では、カテーテル管６と内管１０との間に、第１ルーメン１４が形成してある。第１ルーメン１４には、分岐部８に形成してある拡張ポート１６が連通し、そこから圧力流体が導入され、折り畳まれたバルーン膜４を膨らますようになっている。

【００２６】拡張ポート１６を通して第１ルーメン１４内に導入される圧力流体としては、特に限定されないが、たとえば放射線不透過性色素と塩類との５０／５０混合水溶液などが用いられる。放射線不透過性色素を含ませるのは、バルーンカテーテル２の使用時に、放射線を用いてバルーン膜４およびカテーテル管６の位置を造影するためである。バルーン膜４を膨らますための圧力流体の圧力は、特に限定されないが、絶対圧で３～１２気圧、好ましくは、４～８気圧程度である。

【００２７】分岐部８には、拡張ポート１６とは別個に、内管１０の軸心に沿ってガイドポート１８が形成してある。このガイドポート１８が、内管１０内に形成してある第２ルーメン１２内に連通するように、内管１０の基端部側開口端が分岐部８に接続してある。カテーテル管６と分岐部８との接続および内管１０と分岐部８との接続は、熱融着または接着などの手段により行われる。

【００２８】カテーテル管６は、ある程度の可撓性を有する材質で構成されることが好ましく、たとえばポリエチレン、ポリエチレンテレフタレート、ポリプロピレン、エチレン－プロピレン共重合体、エチレン－酢酸ビニル共重合体、ポリ塩化ビニル（ＰＶＣ）、架橋型エチレン－酢酸ビニル共重合体、ポリウレタン、ポリアミド、ポリアミドエラストマー、ポリイミド、ポリイミドエラストマー、シリコーンゴム、天然ゴムなどが使用でき、好ましくは、ポリエチレン、ポリアミド、ポリイミドで構成される。カテーテル管６の外径は、軸方向に均一でも良いが、バルーン膜４側近傍で小さく、その他の部分で大きくなるように、途中に段部またはテーパ部を形成しても良い。第１ルーメン１４の流路断面を大きくすることにより、バルーン膜４を収縮させる時間を短縮するためである。バルーン膜４は、約１分程度膨張した後、すぐに収縮させることが必要だからであり、末梢側への血流を確保するためである。

【００２９】カテーテル管６の外径は、バルーン膜４との接続部近傍では、０．６～１．０㎜程度が好ましく、分岐部８側では、０．８～１．２㎜程度が好ましい。カテーテル管６の肉厚は、０．０５～０．１５㎜程度が好ましい。内管１０は、たとえばカテーテル管６と同様な材質で構成されて良く、好ましくはポリエチレン、ポリアミド、ポリイミドで構成される。なお補強材として、ステンレス線、ニッケル・チタン合金線などが用いられることもある。この内管１０の内径は、ガイドワイヤを挿通できる径であれば特に限定されず、たとえば０．１５～１．００㎜、好ましくは０．２５～０．６０㎜であ

る。この内管１０の肉厚は、０．０５～０．１５㎜が好ましい。内管１０の全長は、血管内に挿入されるバルーンカテーテル２の軸方向長さなどに応じて決定され、特に限定されないが、たとえば１２０～１５０㎜、好ましくは１３０～１４０㎜程度である。内管１０の先端部には、開口端２０が形成してある。この開口端２０から内管１０の第２ルーメン１２内を挿通したガイドワイヤを、導き出すことが可能になっている。

【００３０】バルーン膜４内に位置する内管１０の周囲には、一箇所または複数箇所に放射線不透過性マーカーを装着することもできる。このマーカーとしては、たとえば金、白金、タングステン、イリジウムあるいはこれらの合金などで構成される金属チューブ、金属スプリングなどをもちいることができる。このマーカーをバルーン膜内の内管１０の周囲に付けることにより、バルーンカテーテル２の使用時のＸ線透視下で、バルーン膜４の位置やバルーンの拡張部分の長さを検出することができる。

【００３１】分岐部８は、たとえばポリカーボネート、ポリアミド、ポリサルホン、ポリアクリレート、メタクリレートーブチレンースチレン共重合体などの熱可塑性樹脂で好適に成形される。本実施例では、バルーン膜４は、図１，２に示すように、軸方向に均一な外径R_1（バルーン膜膨張時）を有する筒状のバルーン膜中央部２２と、その両端部に設けられ、バルーン膜中央部２２よりも小さい外径R_3，R_3'をそれぞれ有する筒状の先端部７および基端部５とを有する。先端部７および基端部５とバルーン膜中央部２２とは、外径が軸方向に除々に縮径してあるテーパ部２４，２６により連続的に成形してある。

【００３２】バルーン膜４のバルーン膜中央部２２での膜厚t_1は、特に限定されないが、１５～２００μm、好ましくは数十μm程度が好ましい。バルーン膜４は、筒状であれば、特に限定されず、円筒または多角筒形状でも良い。また、膨張時のバルーン膜４のバルーン膜中央部２２での外径R_1は、血管の内径などの因子によって決定され、１．５～４．０㎜程度が好ましい。このバルーン膜４のバルーン膜中央部２２の軸方向長さＬは、血管内狭窄部の大きさなどの因子によって決定され、特に限定されないが、１５～５０㎜、好ましくは２０～４０㎜である。膨張する前のバルーン膜４は、図１に示す内管１０の周囲に折り畳まれて巻き付けられ、カテーテル管６の外径と同等以下になっている。

【００３３】バルーン膜４を構成する材質は、ある程度の可撓性を有する材質であることが好ましく、たとえばポリエチレン、ポリエチレンテレフタレート、ポリプロピレン、エチレン－プロピレン共重合体、エチレン－酢酸ビニル共重合体、ポリ塩化ビニル（ＰＶＣ）、架橋型エチレン－酢酸ビニル共重合体、ポリウレタン、ポリアミド、ポリアミドエラストマー、ポリイミド、ポリイミドエラストマー、シリコーンゴム、天然ゴムなどが使用でき、好ましくは、ポリエチレン、ポリエチレンテレフタレート、ポリアミドである。

【００３４】本実施例では、図２に示すように、バルーン膜４の先端部７の外径および中央部２２の外径を、それぞれR_3およびR_1とし、バルーン膜４の先端部７および中央部２２の膜厚を、それぞれt_3およびt_1とした場合に、これらR_3、R_1、t_3およびt_1の関係が、下記（１）式を満足するように設定してある。下記（１）式を満足するようにバルーン膜を製造するための方法については後述する。

【００３５】

【数３】

$$R_1 \times t_1 - t_1 \geq 0.9 \times (R_3 \times t_3 - t_3{}^2) \quad \cdots\cdots \quad (1)$$

なお、従来のバルーンカテーテルのバルーン膜では、通常のブロー成形でバルーン膜が製造されることから、後述の図３に示されるように下記（２）式の関係にあった。

【００３６】

【数４】

$$R_1 \times t_1 - t_1{}^2 = R_3 \times t_3 - t_3{}^2 \quad \cdots\cdots \quad (2)$$

上記（２）式の意味は、たとえば図２において、バルーン膜４の中央部２２での膜横断面の面積（式２の左辺）が、バルーン膜４の先端部７での膜横断面の面積（式２の右辺）に等しいことである。従来のバルーン膜は、軸方向均一肉厚のパリソンをブロー成形することにより成形されるので、上記（２）式が成り立つ。

【００３７】本実施例では、後述するような製法を採用することにより、上記バルーン膜４を製造することから、上記（１）式を満足するように、バルーン膜４の先端部７の膜厚t_3を薄くできた。なお、本実施例では、バルーン膜４の基端部５の肉厚t_3'に関しても、下記（３）式を満足するように、薄く成形できる。

【００３８】

【数５】

$$R_1 \times t_1 - t_1{}^2 \geq 0.9 \times (R_3' \times t_3' - t_3'^2) \quad \cdots\cdots (3)$$

次に、図２に示すバルーン膜４の製造方法について説明する。まず、図３（Ａ）に示すように、肉厚および外径R_0が軸方向で均一なチューブ状のパリソン４ａを準備する。パリソン４ａの外径R_0は、特に限定されないが、０．２～２．０㎜、好ましくは０．５～１．５㎜である。また、パリソン４ａの肉厚は、特に限定されないが、０．２～０．９㎜、好ましくは０．３～０．７㎜である。パリソン４ａの長さL_0は、特に限定されないが、１０～５００㎜、好ましくは２０～３００㎜である。

【0039】次に、図3（B）に示すように、パリソン4ａの両端部5ａ，7ａを薄肉加工する。薄肉加工の方法としては、パリソン4ａの両端部5ａ，7ａを加熱して成形ダイに通す方法と、パリソン4ａの両端部5ａ，7ａを機械加工により切削加工する方法とを例示することができる。成形ダイに通す方法では、マンドレルを用いることにより、パリソン4ａの内径は、変化しない。切削加工は、作業が容易であると共に、確実にパリソンの両端部を薄肉加工することができることから好ましい。

【0040】薄肉加工後の両端部5ａ，7ａの外径は、0．2～1．6㎜、好ましくは0．4～1．2㎜である。その肉厚は、パリソン中央部での肉厚に対して、50～400％、好ましくは100～300％であり、具体的には0．05～0．40㎜、好ましくは0．1～0．3㎜である。また、薄肉加工される両端部5ａ，7ａの長さ範囲L_1は、1～100㎜、好ましくは2～50㎜である。

【0041】その後、この両端部が薄肉加工されたパリソンを、ブロー成形用金型内に装着し、加熱しながら、パリソン4ａの内部に圧力気体あるいは圧力液体を流し、ブロー成形を行い、図2に示すような形状のバルーン膜4を形成する。次に、図1に示す実施例のバルーンカテーテル2を用いて、ＰＴＣＡ治療を行う方法について説明する。

【0042】まず、バルーンカテーテル2内の空気をできる限り除去する。そこで、分岐部8のガイドポート18から内管10内の第2ルーメン12に生理食塩水などの液体を入れ、第2ルーメン12内の空気を置換する。また、分岐部8の拡張ポートには、シリンジなどの吸引・注入手段を取り付け、シリンジ内に血液造影剤（たとえばヨウ素含有）などの液体を入れ、吸引および注入を繰り返し、第1ルーメン14およびバルーン膜4内の空気を液体と置換する。

【0043】バルーンカテーテル2を動脈血管内に挿入するには、まず、セルジンガー法などにより、血管内にガイドカテーテル用ガイドワイヤ（図示せず）を、その先端がたとえば心臓の近くまで届くように挿入する。その後、ガイドカテーテル用ガイドワイヤに沿って、図4に示すガイドカテーテル32を、動脈血管34内に挿入し、その先端を狭窄部36を有する心臓38の冠動脈入口40に位置させる。なお、狭窄部36は、たとえば血栓または動脈硬化などにより形成される。

【0044】次に、ガイドカテーテル用ガイドワイヤのみを抜き取り、それよりも細いバルーンカテーテル用ガイドワイヤ42をガイドカテーテル32に沿って挿入し、その先端を狭窄部36を通過する位置まで差し込む。その後、図4に示すガイドワイヤ42の基端を、図1に示すバルーンカテーテル2の開口端20に差し込み、内管10の第2ルーメン12内に通し、バルーン膜4が折り畳まれた状態で、バルーンカテーテル2を、図4に示すガイドカテーテル32内に通す。そして、バルーンカテーテル2のバルーン膜4を、図4に示すように、狭窄部36の手前まで差し込む。あるいはガイドカテーテル32からガイドカテーテル用ガイドワイヤを抜きとった後、分岐部のガイドポート18より内管の第2ルーメン12内にガイドワイヤを挿通したバルーンカテーテルを、図4に示すガイドカテーテルの基部より挿入して、バルーン膜4を冠動脈内に導き、ガイドワイヤ42の先端を、狭窄部36を通過する位置まで差し込んでもよい。

【0045】その後、図5（Ａ）に示すように、バルーンカテーテル2の最先端に形成されたバルーン膜の先端部7をガイドワイヤ42に沿って、狭窄部36間に差し込む。その際に、本実施例では、バルーン膜4の先端部7の膜厚が薄いことから、その外径が小さく、ガイドワイヤ42と狭窄部36との間隙が小さい場合、強い狭窄部、あるいは硬い狭窄部などでも、図5（Ｂ），（Ｃ）に示すように、容易にバルーンカテーテル2を押し進めることができる。バルーンカテーテル2を狭窄部36内に押し進める際に発生する反力は、図4に示すガイドカテーテル32の先端側曲折部44が血管34の内壁に当接することにより受けるので、この反力が小さいことが好ましい。本実施例では、この反力が小さくなる。

【0046】次に、図5（Ｃ）に示すように、バルーン膜4の位置をＸ線透視装置などで観察しながら、狭窄部36の中央部にバルーン膜4を正確に位置させる。その位置でバルーン膜4を膨らますことにより、血管34の狭窄部36を広げ、良好な治療を行うことができる。なお、バルーン膜4を膨らますには、図1に示す拡張ポート16から第1ルーメン14を通して、バルーン膜4内に造影剤などの液体を注入することにより行う。

【0047】この膨張時間は、特に限定されないが、たとえば約1分間程度である。その後、迅速にバルーン膜4から液体を抜いてバルーン膜を収縮させ、拡張された狭窄部36の末梢側の血流を確保する。バルーン膜4の膨張は、通常は、同一狭窄部36に対して一回であるが、狭窄部36の条件によっては、複数回でも良い。

【0048】次に、本発明の他の実施例について説明する。

第2実施例

本実施例は、図2に示すバルーン膜4のその他の製造方法に関する。バルーン膜4の製造方法以外は、上記第1実施例と同様であるので、その説明は省略する。

【0049】本実施例では、図6に示すように、第1パリソン28の中央部外周に、第2パリソン30を装着し、これらを接着または熱融着することにより、両端部が縮径されたパリソン4ｂを準備する。パリソン4ｂは、結果として、図3（Ｂ）に示すパリソン4ａと同一寸法を有する。

【００５０】その後は、第１実施例と同様にして、図２に示すバルーン膜４を形成することができる。

第３実施例

本実施例では、従来と同様な方法でバルーン膜を製造した後、バルーン膜の筒状先端部および筒状基端部の外周を機械切削加工する方法、あるいはバルーン膜の筒状先端部および筒状基端部を加熱しつつ成形ダイに通す方法により、それらの薄肉加工を行う。このような方法によっても、上記第１実施例に係る図２に示すバルーン膜４を製造することができる。

【００５１】その他の製法および構造は、上記第１実施例と同様である。

第４実施例

図７に示す実施例に係るバルーンカテーテル２Ａは、図１に示す実施例のバルーンカテーテル２に比較し、バルーン膜４Ａ、内管１０Ａおよびこれらの先端部の接合構造が相違するのみであり、その他の構成は同一である。そこで、図１に示す実施例のバルーンカテーテル２と共通する部材には、同一符号を付し、その説明を一部省略する。また、バルーン膜４Ａおよび内管１０Ａの材質および寸法などに関しては、以下に特別に記す以外は、上記第１実施例と同様である。

【００５２】本実施例のバルーンカテーテル２Ａでは、バルーン膜４Ａは、図２に示すバルーン膜と同様に、その先端部７ｂおよび基端部５ｂが、上記（１）式および（２）式を満足するように、従来に比べて薄く成形することが好ましい。ただし、本実施例では、その部分がポイントではないので、バルーン膜４Ａの先端部７ｂおよび基端部５ｂは、従来と同様な膜厚でも良い。

【００５３】本実施例では、図８（Ａ），（Ｂ）に示すように、内管１０Ａの先端部７０の外径を、その他の部分（図７に示すバルーン膜４Ａの中央部に位置する内管１０Ａ）の外径に比較して、小さく縮径してある。内管１０Ａの内径は、ガイドワイヤが挿通されることから、軸方向に略一定であることが好ましい。そのため、内管１０Ａの先端部７０では、その肉厚が、他の部分よりも薄くなる。

【００５４】内管１０Ａの内径は、前記第１実施例の場合と同様に、たとえば０．１５～１．００mm、好ましくは０．２５～０．６０mmである。また、先端部７０以外の内管１０Ａの肉厚は、０．０５～０．１５mmであり、先端部７０での肉厚は、この先端部７０以外の肉厚に対して、３０～７０％が好ましく、具体的には、０．０５～０．１０mmが好ましい。

【００５５】内管１０Ａにおける縮径された先端部７０の長さL_2は、図１に示すバルーン膜４Ａの先端部７ｂとの接続部に相当する長さ、あるいは、それよりも長い長さであることが好ましく、具体的には、２～２０mmが好ましい。内管１０Ａの先端部７０を、縮径するための手段としては、機械的切削加工、あるいは成形ダイおよびマンドレルを用いた引き抜き延伸加工あるいは押し出し延伸加工などを用いることができる。

【００５６】本実施例に係るバルーンカテーテル２Ａでは、内管１０Ａの先端部７０の外径のみを小さく縮径してあり、その部分にバルーン膜４Ａの先端部７ｂが接着または熱融着してあることから、バルーンカテーテル２Ａの先端部の外径が小さくなる。また、内管１０Ａの先端部７０が薄肉になり、その部分の柔軟性が向上する。その結果、本実施例のバルーンカテーテル２Ａでは、血管に対して偏心した狭窄部、あるいは蛇行した狭窄部であっても、バルーンカテーテル２Ａの先端が柔軟に曲折することにより、ガイドワイヤに沿って良好に押し進めることができる。

【００５７】なお、本発明は、上述した実施例に限定されるものではなく、本発明の範囲内で種々に改変することができる。たとえば、上記各実施例では、本発明に係るバルーンカテーテルをＰＴＣＡ治療法に用いる場合を例として説明したが、本発明に係るバルーンカテーテルは、狭窄部などが形成された血管あるいはその他の体腔を拡張するために、広く用いることができる。

【００５８】次に、本発明を、さらに具体的に説明するが、本発明は、これら実施例に限定されない。

実施例１及び比較例１

ナイロン１１のチューブを用いてバルーンを成形した。

【００５９】使用したナイロン１１の線弾性率は約４５００kg/cm であった。図１０に示すように両端部の機械切削加工を行い、R_1 が１．１２５mm、$R_3 = R_3'$ が１．０７２mm、R_d が０．３２５mm、$t_3' = t_3$ が０．３７４mm、t_1 が０．４mm、Ｌａが４０mm、Ｌｂが３０mm、Ｌｃが２０mmの寸法のバルーン成形前のチューブを用意した。

【００６０】このチューブを型に入れ、１８４℃、７kg/cm^2で約１０秒間、加熱加圧を行いバルーン膜を成形した。成形後、切削機を用いて先端部及び手元部を切削した。切削後のバルーン膜（実施例１）は、中央部の外径が３mm、肉厚が０．１mmであり、先端部の外径が１．２mm、肉厚が０．３０mmとなった。また、手元部の寸法は、外径が１．３６mm、肉厚０．２３mmであった。なお、型内での加熱加圧後に両端部を切削しない以外は前述と同様にして成形後のバルーン膜（比較例１）の寸法は、先端部の外径が１．４２mm、肉厚が０．４２mm、手元部の外径が１．６０mm、肉厚が０．３５mmであった。

【００６１】この２種類のバルーン膜（実施例１と比較例１）を、それぞれポリエチレン製の外管と内管からなるカテーテルチューブに接続した。用いたポリエチレンの線弾性係数は約１０００kg/cm であった。バルーン膜の先端部を接続した内管チューブは、外径０．６mm、肉厚０．０８mmのものであり、手元端部を接続した外管チューブは外径０．９mm、肉厚０．０８mmのものであった。接着剤としては、弾性ポリウレタンゴムを用いた。

なお、本実施例においては、$R_1 \times t_1 - t_1^2 = 0.29$であり、$0.9(R_s \times t_s - t_s^2) = 0.24$＊＊３であり、

$$式\quad R_1 \times t_1 - t_1^2 \geq 0.9(R_s \times t_s - t_s^2)\ ...\ (1)$$

の条件を満足する。

【００６２】一方、比較例１では、$R_1 \times t_1 - t_1^2 = 0.29$であり、$0.9(R_s \times t_s - t_s^2) = 0.378$であり、上記（１）式を満たしていない。次に、温水中に浸漬した内径２．５mm、曲率半径１０mmに曲げて血管を模して作成したポリ塩化ビニル製硬質チューブ内に、実施例１および比較例１のバルーンカテーテルを挿通する実験を行った。

【００６３】各々１０回試みた結果を示す。

【００６４】

【表１】

	挿通した	挿通せず
（両端加工例）実施例１	8	2
（両端未加工例）比較例１	3	7

【００６５】上記表に示す如く、この差は、バルーン先端の寸法、特に先端肉厚に起因する。実施例１と比較例１とでは、先端付近での肉厚差はわずかであるが、曲率半径１０mmと強く歪曲した血管を模した硬質チューブ内に挿通させた時、本実施例では、カテーテル先端の剛性※※が構造力学上低くなる。

【００６６】柔らかいカテーテルチューブによって押し込む力の伝達が制限される条件下では、本実施例１と比較例１とでは、挿通し易さに差が生じたものと考えられる。なお、実際の臨床においては、血管内径も著しく狭窄していることもあり、その時には、本実施例によるバルーン先端外径が小さいこともカテーテルの挿通性に有利に働くと考えられる。

【００６７】実施例２

図１０に示すチューブにおいて、R_1が１．１２５mm、R_dが０．３２５mm、$t_s = t_s'$が０．３４６mm、t_1が０．４mm、$R_s = R_s'$が１．０１７mm、という寸法のナイロン１１のチューブを作成した。このチューブを用いて、実施例１と同様にバルーン膜を成形し、成形後両端部を切削加工した。バルーンの先端部、中央部、手元部側の外径、肉厚は各々、１．１３mm（外径）／０．２７mm（肉厚）、３．００mm（外径）／０．１０mm（肉厚）、１．３２mm（外径）／０．２１mm（肉厚）であった。本実施例においては、$R_1 \times t_1 - t_1^2 = 2.9$であり、$0.9(R_s \times t_s - t_s^2) = 0.20897$であり、

$$式\quad R_1 \times t_1 - t_1^2 \geq 0.9(R_s \times t_s - t_s^2)\ ...\ (1)$$

の条件を満足している。このバルーン膜を実施例１に示したカテーテルに接続し、実施例１に示した模擬血管への挿入を１０回試みた。結果を表２に示す。

【００６８】

【表２】

	挿通した	挿通せず
実施例２	１０	0

【００６９】実施例３、４及び比較例２

以下に示すようなナイロン１１のチューブを用意して、バルーン膜を成形した。用いたナイロン１１の線弾性係数は約４５００kg/cm であった。実施例３及び４のチューブは、図１０に例示したように両端を機械的に切削して、所定の外径とした。

【００７０】これらのチューブを型に入れ、実施例１と★★同様に加熱加圧して、バルーンを成形した後、切削機を用いて、先端部及び手元部を切削して所定の外径及び肉厚とした。いずれのバルーン膜も、バルーン中央部の外径は３．０mm、その部分での肉厚は０．１６mmであった。

【００７１】実施例３のバルーン膜を成形するためのチューブ寸法は、図１０において、R_1が１．３７mm、$R_s = R_s'$が１．０７３mm、R_dが０．３２５mm、$t_s = t_s'$が０．３７４mm、t_1が０．５３mmである。成形後のバルーン膜のバルーン中央部の外径は３．０mm、肉厚は０．１６mmで、先端部では外径１．２０mm、肉厚０．３０mm、手元部では外径１．３６mm、肉厚０．２３mmである。本実施例においては、$R_1 \times t_1 - t_1^2 = 0.4544$であり、$0.9(R_s \times t_s - t_s^2) = 0.243$であり、

$$式\quad R_1 \times t_1 - t_1^2 \geq 0.9(R_s \times t_s - t_s^2)\ ...\ (1)$$

の条件を満足している。実施例４のバルーン膜を成形するためのチューブ寸法は、図１０において、R_1が１．３９mm、$R_s = R_s'$が１．３１mm、R_dが０．３２５mm、$t_s = t_s'$が０．４９５mm、t_1が０．５３mmである。成形後のバルーン膜のバルーン中央部の外径は☆☆３．０mm、肉厚は０．１６mmで、先端部では外径１．４１mm、肉厚０．４０mm、手元部では外径１．５６mm、肉厚０．３３mmである。本実施例においては、$R_1 \times t_1 - t_1^2 = 0.4544$であり、$0.9(R_s \times t_s - t_s^2) = 0.3636$であり、

$$式\quad R_1 \times t_1 - t_1^2 \geq 0.9(R_s \times t_s - t_s^2)\ ...\ (1)$$

の条件を満足している。

【００７２】比較例２では、実施例４において、型内での加熱加圧後に両端を切削しない以外は同様にして、バルーン中央部の外径が３．０mm、肉厚が０．１６mm、先

端部では外径1．57mm、肉厚0．48mm、手元部では外径1．71mm、肉厚0．40mmのバルーン膜を成形した。

【0073】本比較例においては、$R_1 \times t_1 - t_1{}^2 = 0.4544$であり、$0.9(R_s \times t_s - t_s{}^2) = 0.47088$であり、

$$式\ R_1 \times t_1 - t_1{}^2 \geqq 0.9(R_s \times t_s - t_s{}^2) \ldots (1)$$

の条件を満足していない。これらの種類のバルーン膜を実施例1と同様にしてポリエチレン製カテーテルチューブに接続した。

【0074】用いたポリエチレンの線弾性係数は約1000kg/cm であった。バルーン先端部に接続した内管チューブは、外径0．6mm、肉厚0．08mmのもの、バルーン手元端部に接続した外管チューブは外径0．9mm、肉厚0．08mmのものであった。接着剤としては、弾性ポリウレタンゴムを用いた。

【0075】次に、温水中に浸漬した内径2．5mm、曲率半径10mmに曲げて血管を模して作ったポリ塩化ビニル製硬質チューブ内に、これら実施例および比較例のバルーンカテーテルを挿通する実験を行った。各々、10回試みた結果を表3に示す。

【0076】

【表3】

	挿通した	挿通せず
実施例3	10	0
実施例4	8	2
比較例2	2	8

【0077】表3に示すように、実施例と比較例とでは、挿入特性に大幅な差が見られた。この差は、バルーン先端の寸法、特に肉厚に起因する。実施例と比較例では、先端付近での肉厚差はわずか0．08mmであるが、曲率半径10mmと強く歪曲した血管を模した硬質チューブ内に挿通させた時、本実施例では、カテーテル先端の剛性が低い。

【0078】柔らかいカテーテルチューブによって押し込む力の伝達が制限される本条件下では、実施例4の方が比較例と比べて挿通し易さに差を生じたものと考えられる。実施例3が特に優れていたのは、同じ理由による。なお、実際の臨床においては、血管内径も著しく狭窄していることもあり、その時は、本実施例によるバルーン先端外径が小さいこともカテーテルの挿通性に有利に働くものと考えられる。

【0079】<u>実施例5及び比較例3</u>

加熱したダイにチューブを通す方法で、図10に示すR_1が1．125mm、$R_s{}' = R_s$が1．017mm、R_dが0．325mm、$t_s = t_s{}'$が0．346mm、t_1が0．4mmのナイロン11のチューブを作成した。

【0080】このチューブを用いて、実施例1と同様に金型で加熱加圧成形した後、先端部および手元部を切削機で切削し、バルーン膜を作成した。バルーン膜の先端部、中央部、手元部側の外径、肉厚は各々、1．13mm（外径）／0．27mm（肉厚）、3．00mm（外径）／0．10mm（肉厚）、1．32mm（外径）／0．21mm（肉厚）となった。本実施例においては、$R_1 \times t_1 - t_1{}^2 = 0.29$であり、$0.9(R_s \times t_s - t_s{}^2) = 0.209$であり、

$$式\ R_1 \times t_1 - t_1{}^2 \geqq 0.9(R_s \times t_s - t_s{}^2) \ldots (1)$$

の条件を満足している。これに先の実施例3及び4に示したポリエチレン製カテーテルチューブを接続した。

【0081】また、比較例として両端の肉厚を減らさないまま（切削しないで）成形したバルーン膜を同様に前記ポリエチレン製カテーテルチューブに接続した。先端部、中央部及び手元部の寸法は、外径、肉厚が1．48mm（外径）／0．44mm（肉厚）、3．00mm（外径）／0．10mm（肉厚）、1．64mm（外径）／0．37mm（肉厚）であった。

【0082】比較例においては、$R_1 \times t_1 - t_1{}^2 = 0.29$であり、$0.9(R_s \times t_s - t_s{}^2) = 0.412$であり、

$$式\ R_1 \times t_1 - t_1{}^2 \geqq 0.9(R_s \times t_s - t_s{}^2) \ldots (1)$$

の条件を満足していない。これらのカテーテルを実施例3等で用いた模擬血管への挿入を各々10回試みた。結果を表4に示す。

【0083】

【表4】

	挿通した	挿通せず
実施例5	10	0
比較例3	3	7

【0084】<u>実施例6</u>

外径0．6mm、肉厚0．08mmのチューブの先端部のみを、切削加工等で縮径し、外径0．52mm、肉厚0．04mmとし（その他の部分では外径0．6mm、肉厚0．08mm）、バルーンカテーテルの内管を成形した。

【0085】これとは別に、実施例4と同様にして、図10に示すR_1が1．39mm、$R_s = R_s{}'$が1．31mm、R_dが0．325mm、$t_s = t_s{}'$が0．495mm、t_1が0．53mmのチューブを切削加工により形成した。このチューブを、金型内で加熱加圧成形した後、切削加工し、バルーン膜の先端部、中央部および手元部の寸法が、1．37mm（外径）／0．43mm（肉厚）、3．00mm（外径）／0．16mm（肉厚）、1．56mm（外径）／0．33mm（肉厚）のバルーン膜を成形し

た。

【0086】このバルーン膜を、前記バルーンカテーテルの内管（内管の先端部が細くなったチューブ）および外管（実施例1に同じ）に接続し、実施例1と同様にカテーテルを組立て、実施例1と同じ方法で試験を行った。結果を表5に示す。

【0087】

【表5】

	挿通した	挿通せず
実施例6	9	1

【0088】本実施例では内管チューブを縮径したことにより、バルーンの先端外径が実施例4と比べて0．04mm（約3％）細くなっている。このことは、実際の臨床において、狭塞した血管への適用時に、挿通性が良いことが期待される。

【0089】

【発明の効果】以上説明してきたように、本発明によれば、血管などの体腔に形成された狭窄部が狭い場合、狭窄部が硬い場合、狭窄部が偏心または蛇行している場合でも、バルーンカテーテルのバルーン膜を体腔の狭窄部位置まで低操作力で容易にしかも正確に進めることができ、バルーンカテーテルの体腔拡張機能を有効に発揮させることができる。

【0090】本発明に係るバルーンカテーテルの製造方法では、バルーン膜中央部でのバルーン膜の耐圧を低下させることなく、バルーン膜の先端部膜厚を薄く成形することが可能になる。

【図面の簡単な説明】

【図1】図1は本発明の一実施例に係るバルーンカテーテルの概略断面図である。

【図2】図2は図1に示すバルーンカテーテルに用いるバルーン膜の断面図である。

【図3】図3（A），（B）は図1に示すバルーン膜を製造するためのパリソンを示す斜視図である。

【図4】図4は図1に示すバルーンカテーテルの使用方法を示す概略図である。

【図5】図5（A）～（C）は図1に示すバルーンカテーテルの使用方法を示す要部断面図である。

【図6】図6は本発明の他の実施例に係るバルーンカテーテルのバルーン膜を製造するためのパリソンの断面図である。

【図7】図7は本発明の他の実施例に係るバルーンカテーテルの概略断面図である。

【図8】図8（A），（B）は図7に示す内管の先端部の要部斜視図および断面図である。

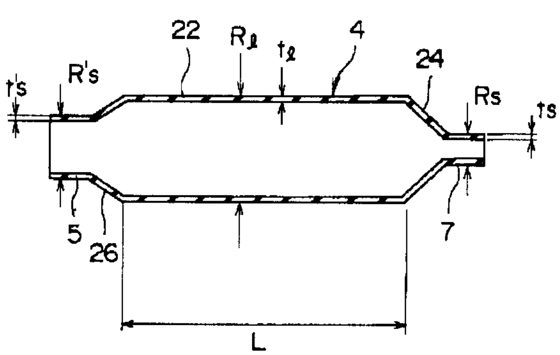
【図9】図9は従来例に係るバルーンカテーテルに用いるバルーン膜の断面図である。

【図10】図10は本発明の実施例および比較例に係るバルーンカテーテルのバルーン膜を製造するためのパリソンの寸法を示す斜視図である。

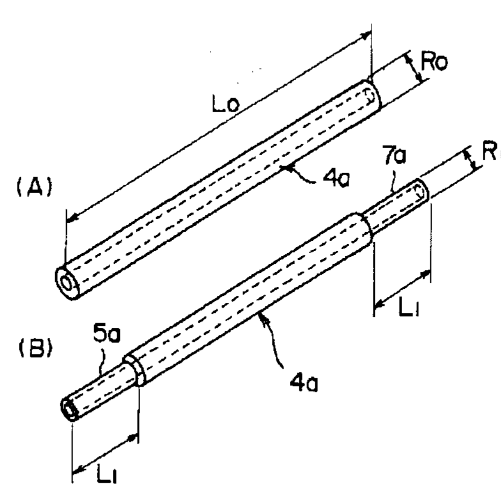
【符号の説明】

2，2A… バルーンカテーテル
4，4A… バルーン膜
5，5b… 基端部
6… カテーテル管
7，7b… 先端部
8… 分岐部
10，10A… 内管
12… 第2ルーメン
14… 第1ルーメン
20… 開口端
22… バルーン膜中央部
24，26… テーパ部
32… ガイドカテーテル
34… 大動脈
36… 狭窄部

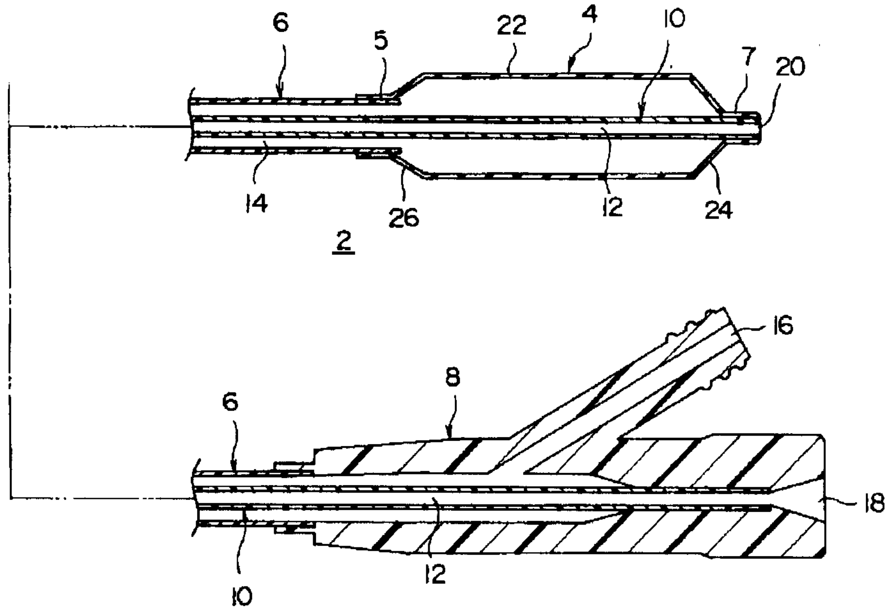
【図2】



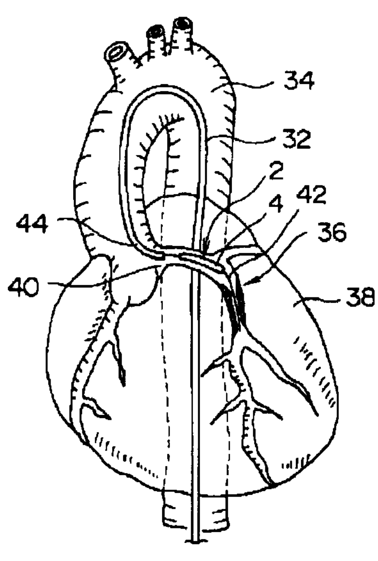
【図3】



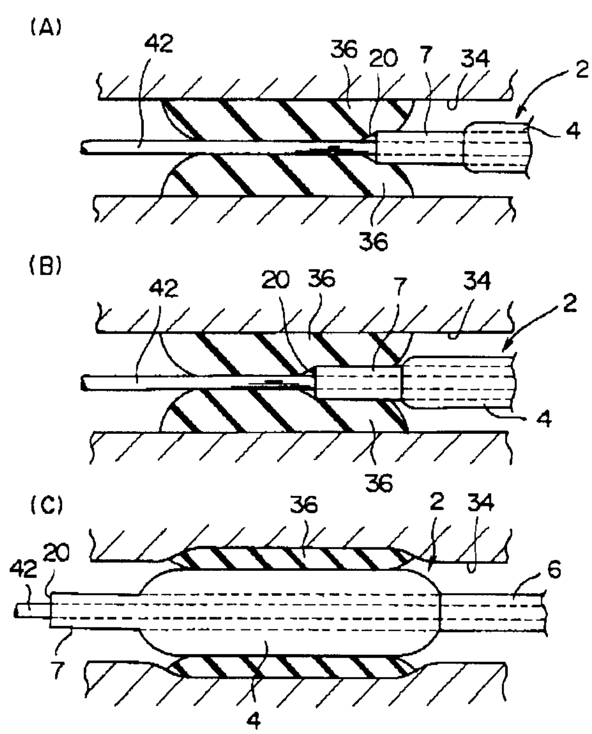
【図1】


6
5
22
4
10
7
20
14
26
12
24
2
16
8
6
18
10
12

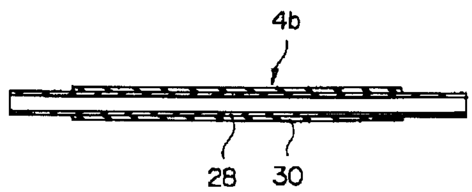
【図4】


34
32
2
4
42
44
36
40
38

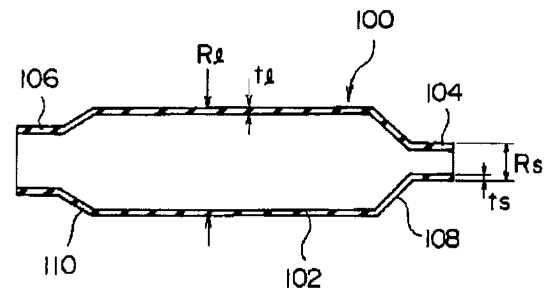
【図5】


(A)
42
36
20
7
34
2
4
36
(B)
42
20
36
7
34
2
4
36
(C)
36
2
34
42
20
6
7
4

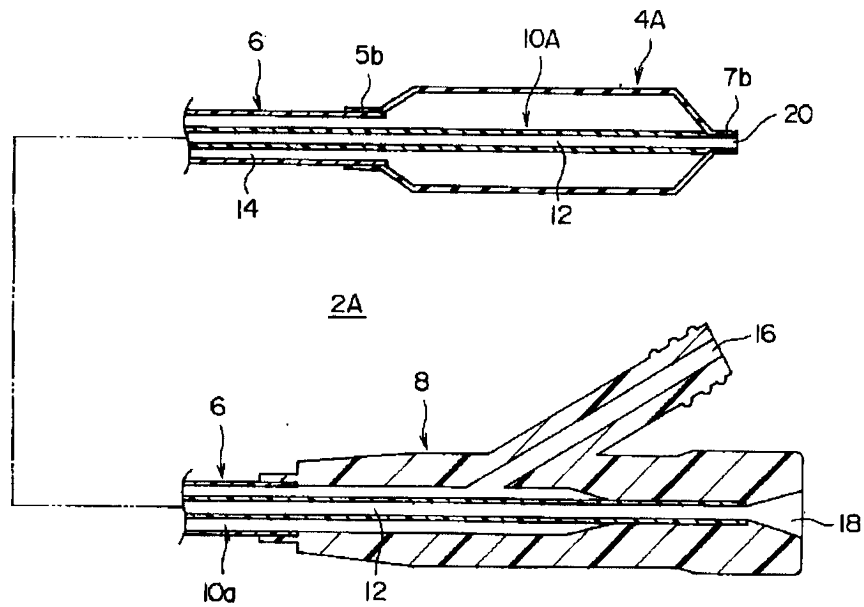
【図6】



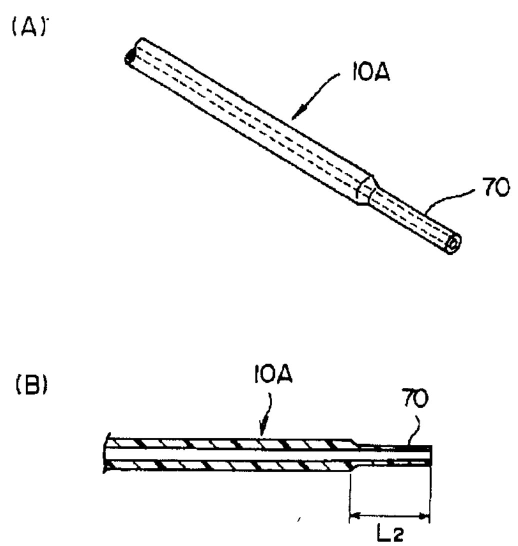
【図9】



【図7】



【図8】



【図10】